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LEGAL COMPILATION: STATUTES AND LEGISLATIVE HISTORY, EXECUTIVE ORDERS, REGULATIONS, GUIDELINES AND REPORTS. E. PESTICIDES. VOLUME III

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THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Legal Compilation

Statutes and Legislative History
Executive Orders
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JANUARY 1973

WILLIAM D. RUCKELSHAUS
Administrator

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FOREWORD

It has been said that America is like a gigantic boiler in that once the fire is lighted, there are no limits to the power it can generate. Environmentally, the fire has been lit!

With a mandate from the President and an aroused public concern over the environment, we are experiencing a new American Revolution, a revolution in our way of life. The era which began with the industrial revolution is over and things will never be quite the same again. We are moving slowly, perhaps even grudgingly at times, but inexorably into an age when social, spiritual and aesthetic values will be prized more than production and consumption. We have reached a point where we must balance civilization and nature through our technology.

The U.S. Environmental Protection Agency, formed by Reorganization Plan No. 3 of 1970, was a major commitment to this new ethic. It exists and acts in the public's name to ensure that due regard is given to the environmental consequences of actions by public and private institutions.

In a large measure, this is a regulatory role, one that encompasses basic, applied, and effects research; setting and enforcing standards; monitoring; and making delicate risk-benefit decisions aimed at creating the kind of world the public desires.

The Agency was not created to harass industry or to act as a shield behind which man could wreak havoc on nature. The greatest disservice the Environmental Protection Agency could do to American industry is to be a poor regulator. The environment would suffer, public trust would diminish, and instead of free enterprise, environmental anarchy would result.

It was once sufficient that the regulatory process produce wise and well-founded courses of action. The public, largely indifferent to regulatory activities, accepted agency actions as being for the "public convenience and necessity." Credibility gaps and cynicism make it essential not only that today's decisions be wise and well-founded but that the public know this to be true. Certitude, not faith, is de rigueur.

In order to participate intelligently in regulatory proceedings, the citizen should have access to the information available to the agency. EPA's policy is to make the fullest possible disclosure of information, without unjustifiable expense or delay, to any interested party. With this in mind, the EPA Compilation of Legal Authority was produced not only for internal operations of EPA, but as a service to the public, as we strive together to lead the way, through the law, to preserving the earth as a place both habitable by and hospitable to man.

WILLIAM D. RUCKELSHAUS,
Administrator
U.S. Environmental Protection Agency

PREFACE

Reorganization Plan No. 3 of 1970 transferred 15 governmental units with their functions and legal authority to create the U.S. Environmental Protection Agency. Since only the major laws were cited in the Plan, the Administrator, William D. Ruckelshaus, requested that a compilation of EPA legal authority be researched and published.

The publication has the primary function of providing a working document for the Agency itself. Secondarily, it will serve as a research tool for the public.

A permanent office in the Office of Legislation has been established to keep the publication updated by supplements.

It is the hope of the EPA that this set will assist in the awesome task of developing a better environment.

MARY LANE REED WARD GENTRY, J.D.
Assistant Director for Field Operations
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ACKNOWLEDGEMENT

The idea of producing a compilation of the legal authority of EPA was conceived and commissioned by William D. Ruckelshaus, Administrator of EPA. The production of this compilation involved the cooperation and effort of numerous sources, both within and outside the Agency. The departmental libraries at Justice and Interior were used extensively; therefore we express our appreciation to Marvin P. Hogan, Librarian, Department of Justice; Arley E. Long, Land & Natural Resources Division Librarian, Department of Justice; Frederic E. Murray, Assistant Director, Library Services, Department of the Interior.

For exceptional assistance and cooperation, my gratitude to: Gary Baise, formerly Assistant to the Administrator, currently Director, Office of Legislation, who first began with me on this project; A. James Barnes, Assistant to the Administrator; K. Kirke Harper, Jr., Special Assistant for Executive Communications; John Dezzutti, Administrative Assistant, Office of Executive Communications; Roland O. Sorensen, Chief, Printing Management Branch, and Jacqueline Gouge and Thomas Green, Printing Management Staff; Ruth Simpkins, Janis Collier, Wm. Lee Rawls, Peter J. McKenna, James G. Chandler, Jeffrey D. Light, Randy Mott, Thomas H. Rawls, John D. Whittaker, John M. Himmelberg, Dana W. Smith, and Linda L. Payne, and a beautiful staff who gave unlimited effort; and to many others behind the scenes who rendered varied assistance.

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INSTRUCTIONS

The goal of this text is to create a useful compilation of the legal authority under which the U.S. Environmental Protection Agency operates. These documents are for the general use of personnel of the EPA in assisting them in attaining the purposes set out by the President in creating the Agency. This work is not intended and should not be used for legal citations or any use other than as reference of a general nature. The author disclaims all responsibility for liabilities growing out of the use of these materials contrary to their intended purpose. Moreover, it should be noted that portions of the Congressional Record from the 92nd Congress were extracted from the "unofficial" daily version and are subject to subsequent modification.

EPA Legal Compilation consists of the Statutes with their legislative history, Executive Orders, Regulations, Guidelines and Reports. To facilitate the usefulness of this composite, the Legal Compilation is divided into the eight following chapters:

- A. General
- B. Air
- C. Water
- D. Solid Waste
- E. Pesticides
- F. Radiation
- G. Noise
- H. International

PESTICIDES

The chapter labeled "Pesticides" and color coded green contains the legal authority of the Agency as it applies to pesticide pollution abatement. It is well to note that any law which is applicable to more than one chapter of the Compilation will appear in each of the chapters; however, its legislative history will be cross-referenced into the "General" chapter where it is printed in full.

SUBCHAPTERS

Statutes and Legislative History

For convenience, the Statutes are listed throughout the Compilation by a one-point system, i.e., 1.1, 1.2, 1.3, etc., and Legislative History begins wherever a letter follows the one-point system. Thusly, any 1.1a, 1.1b, 1.2a, etc., denotes the public laws comprising the 1.1, 1.2 statute. Each public law is followed by its legislative history. The legislative history in each case consists of the House Report, Senate Report, Conference Report (where applicable), the Congressional Record beginning with the time the bill was reported from committee.

Example:

1.1 The Federal Insecticide, Fungicide, and Rodenticide Acts, as amended, 7 U.S.C. §§135–135k (1970).
  1.1a The Insecticide Act, April 26, 1910, P.L. 61–152, 36 Stat. 331.
    (1) Senate Committee on Agriculture and Forestry, S. REP. No. 436, 61st Cong., 2d Sess. (1910).
    (2) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 990, 61st Cong., 2d Sess. (1910).
    (3) Congressional Record, Vol. 45 (1910):
      (a) April 4: Debated, amended and passed Senate, pp. 4204–4206;
      (b) April 18: Debated, amended and passed House, pp. 4914–4920;
      (c) April 19: Senate agrees to House amendments, p. 4959.

This example not only demonstrates the pattern followed for legislative history, but indicates the procedure where only one section of a public law appears. You will note that the Congressional Record cited pages are only those pages dealing with the discussion and/or action taken pertinent to the section of law applicable to EPA. In the event there is no discussion of the pertinent section, only action or passage, then the asterisk (*) is used to so indicate, and no text is reprinted in the Compilation. In regard to the situation where only one section of a public law is applicable, then only the parts of the report dealing with same are printed in the Compilation.

Secondary Statutes

Many statutes make reference to other laws and rather than have this manual serve only for major statutes, these secondary statutes have been included where practical. These secondary statutes are indicated in the table of contents to each chapter by a bracketed cite to the particular section of the major act which made the reference.

Citations

The United States Code, being the official citation, is used throughout the Statute section of the Compilation.

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1.2	Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§346, 346a, 348 (1970).	Directly cited in Reorg. Plan No. 3 of 1970.
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1.4	The Public Health Service Act, as amended, 42 U.S.C. §241, 243, 246, 264 (1970).	Reorg. Plan No. 3 of 1970.
1.5	Special Packaging of Household Substances for the Protection of Children, 15 U.S.C. §1471 *et seq.* (1970).	In first section of Act, direct reference is made to both FIFRA and the Federal Food, Drug, and Cosmetic Act, section over which we were given authority through Reorg. Plan No. 3 of 1970.
1.6	Hearings: Presiding Employees: Powers and Duties; Burden of Proof; Evidence; Records as a Basis of Decision, 5 U.S.C. §556(c) (1966).	Referred to in the FIFRA at §135b and FD&C Act at §246a(d) (5).
1.7	Record on Review and Enforcement of Agency Orders, as amended, 28 U.S.C. §2112 (1966).	Referred to in FIFRA at §135b(d), and FD&C Act at §346a (i) (2) (3), 348(g) (2), and Special Packaging of Household Substances Act at §1474 (b) (1).
1.8	Courts of Appeals; Certiorari, Appeal; Certified Questions, as amended, 28 U.S.C. §1254 (1948).	Referred to in FIFRA at §135b(d), and FD&C Act at §§346a(i) (5), 348(g) (5), and Special Packaging of Household Substances Act at §1474(b) (5).
1.9	Adulterated Food, as amended, 21 U.S.C. §432(a) (1968).	Referred to in FD&C Act at §§346, 346a(a), 348(a((2).
1.10	Appointment and Compensation of Advisory Committee, Color Additive Amendments of 1960, as amended, 21 U.S.C. §§376(b) (5) (D) (1970).	Referred to in FD&C Act at §346a(g).
1.11	Regulations and Hearings—Authority to Promulgate Regulations, 21 U.S.C. §371 (1960).	Referred to in FD&C Act at §346a(k), and Special Packaging of Household Substances Act at §1474(a).
1.12	Penalties—Violation of §331 of this Title, 21 U.S.C. §333(c) (1970).	Referred to in FD&C Act in §346a(n).

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1.13 Research and Development Act, Contracts, as amended, 10 U.S.C. §§2353, 2354 (1956).	Referred to in Public Health Service Act at §241(h).
1.14 Rule Making, Administrative Procedure, as revised, 5 U.S.C. §553 (1966).	Special Packaging of Household Substances Act at §1474(a),(b).
1.15 Judicial Review, Relief Pending Review; Scope, as revised, 5 U.S.C. §§705, 706(2)(A),(B),(C),(D) (1966).	Special Packaging of Household Substances Act at §1474(b)(3),(4).
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Regulations

The Regulations are noted by a three-point system (3.1, 3.2, etc.). Included in the Regulations are those not only promulgated by the Environmental Protection Agency, but those under which the Agency has direct contact.

Guidelines and reports

This subchapter is noted by a four-point system (4.1, 4.2, etc.). In this subchapter is found the statutorily required reports of EPA, published guidelines of EPA, selected reports other than EPA's and inter-departmental agreements of note.

UPDATING

Periodically, a supplement will be sent to the interagency distribution and made available through the U.S. Government Printing Office in order to provide an accurate working set of EPA Legal Compilation.

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(2) House Committee on Interstate and Foreign Commerce, H.R. REP. No. 91–1444, (Parts 1 and 2), 91st Cong., 2d Sess. (1970). 1174
(3) Committee of Conference, H.R. REP. No. 91–1603, 91st Cong., 2d Sess. (1970). 1176
(4) Congressional Record, Vol. 116 (1970):
(a) Jan. 28: Considered and passed Senate, p. 1690;* 1177
(b) Sept. 24: Considered and passed House, p. 33667;* 1177
(c) Oct. 7: Amended and passed Senate, pp. 35496–35497;* 1177
(d) Oct. 14: House agrees to conference report, p. 36655;* 1177
(e) Oct. 14: Senate agrees to conference report, p. 36885.* 1177
1.14 Research and Development Act, Contracts, as amended, 10 U.S.C. §§2353, 2354 (1956).
[Referred to in 42 U.S.C. §241(h)] 1178
1.14a Armed Forces Research and Development Act, July 16, 1952, P.L. 82–557, §§4, 5, 66 Stat. 725. 1179

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    (1) House Committee on Armed Services, H.R. REP. No. 548, 82nd Cong., 1st Sess. (1951). 1181
    (2) Senate Committee on Armed Services, S. REP. No. 936, 82nd Cong., 1st Sess. (1951). 1194
    (3) Congressional Record:
        (a) Vol. 97 (1951), Aug. 2: Passed House, pp. 9431–9433; 1204
        (b) Vol. 98 (1952), July 3: Amended and passed Senate, pp. 9053–9054; 1210
        (c) Vol. 98 (1952), July [illegible]: House concurs in Senate amendments, pp. 9374–9375. 1212
  1.14b Armed Forces Procurement Amendments of 1956, August 10, 1956, P.L. 84–1028, §§2353, 2354, 70A Stat. 134. 1213
    (1) House Committee on the Judiciary, H.R. REP. No. 970, 84th Cong., 1st Sess. (1955). 1214
    (2) Senate Committee on the Judiciary, S. REP. No. 2484, 84th Cong., 2d Sess. (1956). 1217
    (3) Congressional Record:
        (a) Vol. 101 (1955), Aug. 1: Amended and passed House, pp. 12718–12719; 1218
        (b) Vol. 102 (1956), July 23: Amended and passed Senate, p. 13953;* 1219
        (c) Vol. 102 (1956), July 25: House concurs in Senate amendment, p. 14455.* 1219
1.15 Rule Making, Administrative Procedure, as revised, 5 U.S.C. §553 (1966).
[Referred to in 15 U.S.C. §1474(a), (b)] 1219
  1.15a Rule Making, June 11, 1946, P.L. 97–404, §4, 60 Stat. 238. 1220
    (1) Senate Committee on the Judiciary, S. REP. No. 752, 79th Cong., 1st Sess. (1945). 1221
    (2) House Committee on the Judiciary, H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946). 1230
    (3) Congressional Record, Vol. 92 (1946):
        (a) March 12: Debated, amended and passed Senate, pp. 2151–2152, 2155, 2157, 2161–2162, 2165; 1241
        (b) May 24: Debated, amended and passed House, pp. 5645, 5649; 5650–5652, 5656, 5660–5661; 1244
        (c) May 27: Senate concurs in the House amendments, p. 5788.* 1248
  1.15b Administrative Procedure and Rule Making, September 6, 1966, P.L. 89–554, §553, 80 Stat. 383. 1248
    (1) House Committee on the Judiciary, H.R. REP. No. 901, 89th Cong., 1st Sess. (1965). 1249
    (2) Senate Committee on the Judiciary, S. REP. No. 1380, 89th Cong., 2d Sess. (1966). 1251

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(3) Congressional Record:
(a) Vol. 111 (1965), Sept. 7: Passed House, p. 22954;* 1251
(b) Vol. 112 (1966), July 25: Amended and passed Senate, p. 17010;* 1252
(c) Vol. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077. 1252

1.16 Judicial Review; Relief Pending Review; Scope, as revised, 5 U.S.C. §§705, 706(2) (A), (B), (C), (D) (1966). [Referred to in 15 U.S.C. §1474(b) (3) (4)] 1252

1.16a Judicial Interim Relief and Review of Agencies Acts, June 11, 1946, P.L. 79-404, §10(d), (e), 60 Stat. 243. 1253

(1) Senate Committee on the Judiciary, S. REP. No. 752, 79th Cong., 1st Sess. (1945). 1255
(2) House Committee on the Judiciary, H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946). 1261
(3) Congressional Record, Vol. 92 (1946):
(a) March 12: Amended and passed Senate, pp. 2151, 2153, 2158, 2163, 2166; 1267
(b) May 24: Debated, amended and passed House, pp. 5454-5457, 5660, 5666; 1270
(c) May 27: Senate concurs in House amendments, p. 5790.* 1276

1.16b Judicial Interim Relief and Review of Agency Amendments, September 6, 1966, P.L. 89-554, §§705, 706, 80 Stat. 393. 1276

(1) House Committee on the Judiciary, H.R. REP. No. 901, 89th Cong., 1st Sess. (1965). 1277
(2) Senate Committee on the Judiciary, S. REP. No. 1380, 89th Cong., 2d Sess. (1966). 1279
(3) Congressional Record:
(a) Vol. 111 (1965), Sept. 7: Passed House, p. 22954;* 1279
(b) Vol. 112 (1966), July 25: Amended and passed Senate, pp. 17010, 17011;* 1279
(c) Vol. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077.* 1280

1.17 Per Diem, Travel and Transportation Expenses; Experts and Consultants; Individuals Serving Without Pay, as amended, 5 U.S.C. §5703 (1966).
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1.18 Federal Water Pollution Control Act, as amended, 33 U.S.C. §1155(l) (1), (2) (1970). 1281

1.18a The Water Quality Improvement Act of 1970, April 3, 1970, P.L. 91-224, §105(L), 84 Stat. 111. 1281

(1) House Committee on Public Works, H.R. REP. No. 91-127, 91st Cong., 1st Sess. (1969). 1283

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(2) Senate Committee on Public Works, S. REP. No. 91–351, 91st Cong., 1st Sess. (1969). 1284
(3) Committee of Conference, H.R. REP. No. 91–940, 91st Cong., 2d Sess. (1970). 1285
(4) Congressional Record:
(a) Vol. 115 (1969), April 16: Amended and passed House, p. 9293;* 1286
(b) Vol. 115 (1969), Oct. 7: Senate debated and amended, pp. 28923–28924, 28987–29008; 1286
(c) Vol. 115 (1969), Oct. 8: Passed Senate, p. 29099;* 1338
(d) Vol. 116 (1970), March 24: Senate agrees to conference report; 1338
(e) Vol. 116 (1970), March 25: House agrees to conference report, p. 9334.* 1338
1.18b Federal Water Pollution Control Act Amendments of 1972, October 18, 1972, P.L. 92–500, §104(1), 86 Stat. 822. 1338
(1) Senate Committee on Public Works, S. REP. No. 92–414, 92d Cong., 1st Sess. (1971). 1339
(2) House Committee on Public Works, H.R. REP. No. 92–911, 92d Cong., 2d Sess. (1972). 1344
(3) Committee of Conference, H.R. REP. 92–1465, 92d Cong., 2d Sess. (1972). 1345
(4) Congressional Record:
(a) Vol. 117 (1971), Nov. 2: Considered and passed Senate;* 1345
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1.19 Interest on Certain Government Obligations, as amended, 26 U.S.C. §103 (1969).
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1.20 Amortization of Pollution Control Facilities, as amended, 26 U.S.C. §169 (1969).
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C.F.R. §§162.100–162.125 (1970). 1357
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3.5 FAA Certification of Private Agricultural Operations, Federal Aviation Administration, 14 C.F.R. §137.1–137.77 (1968). 1357
3.6 Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, U.S. Environmental Protection Agency, 40 C.F.R. §180.1–180.1023 (1972). 1357
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4.1 Interdepartmental Agreements. 1361
4.1a Interdepartmental Agreement for Protection of Public Health and Quality of Environment between Departments of Agriculture, Interior, and Health, Education and Welfare concerning economic poisons, March 3, 1970, 35 Fed. Reg. 4014 (1970). 1361
4.1b Agreement Between Department of Health, Education, and Welfare and Environmental Protection Agency, December 22, 1971, 36 Fed Reg. 24234. 1364
4.1c Interagency Agreement Between the Department of Health, Education and Welfare and the Environmental Protection Agency for Joint Participation in the National Center for Toxicological Research, April 1, 1971. 1367
4.1d Memorandum of Agreement Between the United States Environmental Protection Agency and the United States Department of Agriculture, June 14, 1972. 1370
4.1e Interagency Agreement Between the Department of Agriculture and the Environmental Protection Agency, Jan. 23, 1973. 1372
4.2 Selected Reports 1376
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4.2b Deficiencies in Administration of Federal Insecticide, Fungicide, and Rodenticide Act, House Committee on Government Operations, H.R. REP. No. 91–637, 91st Cong., 1st Sess. (1969). 1402
4.2c Report on 2, 4, 5-T, A Report of the Panel on Herbicides of the President's Science Advisory Committee, March 1971. 1495

1.12c (3) CONGRESSIONAL RECORD

1.12c (3) (a) VOL. 93 (1947), July 7: Amended and passed House, p. 8392

[No Relevant Discussion on Pertinent Section]

1.12c (3) (b) VOL. 94 (1948), June 21: Amended and passed Senate, p. 7927

[No Relevant Discussion on Pertinent Section]

1.12c (3) (c) VOL. 94 (1948), June 16: House concurs in Senate amendment, p. 8499

[No Relevant Discussion on Pertinent Section]

1.12d 1953 REORGANIZATION PLAN I, §§5, 8, 67 STAT. 631

Prepared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, March 12, 1953, pursuant to the provisions of the Reorganization Act of 1949, approved June 20, 1949, as amended.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[p. 631]

SEC. 5. *Transfers to the Department.*—All functions of the Federal Security Administrator are hereby transferred to the Secretary. All agencies of the Federal Security Agency, together with their respective functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), and all other functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available) of the Federal Security Agency are hereby transferred to the Department.

SEC. 8. *Abolitions.*—The Federal Security Agency (exclusive of the agencies thereof transferred by section 5 of this reorganization plan), the offices of Federal Security Administrator and Assistant Federal Security Administrator created by Reorganization Plan No. 1 (53 Stat. 1423), the two offices of assistant heads of the Federal Security Agency created by Reorganization Plan No. 2 of 1946 (60 Stat. 1095), and the office of Commissioner for Social Security created by section 701 of the Social Security Act, as amended (64 Stat. 558), are hereby abolished. The Secretary shall make such provisions as may be necessary in order to wind up any outstanding affairs of the Agency and offices abolished by this section which are not otherwise provided for in this reorganization plan.

[p. 632]

1.12e FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS OF 1954

April 15, 1954, P.L. 83–335, §2, 68 Stat. 55

SEC. 2. Section 701 (e) of the Federal Food, Drug, and Cosmetic Act is amended by striking out "401,".

1.12e (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 934, 83rd Cong., 1st Sess. (1953)

AMENDING SECTIONS 401 AND 701 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO ESTABLISHMENT OF FOOD STANDARDS

JULY 24, 1953.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. HALE, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 6434]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 6434) to amend sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the establishment of food standards, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE OF THE LEGISLATION

The bill has a twofold purpose:

(1) To simplify the procedures governing the issuing, amending, or repealing of regulations fixing and establishing definitions and standards of identity, standards of quality, or standards of fill of container, for foods as authorized by section 401 of the Federal Food, Drug, and Cosmetic Act, by restricting the requirements for the formal type of hearings, as now prescribed in section 701 (e) of that act, to instances where this procedure is desired by a party who would be

adversely affected if the regulation, as proposed, were to become effective; and

(2) To enlarge the class of persons who as a matter of right may petition the Secretary to act on a proposal to issue, amend, or repeal, as the case may be, any such regulation. [p. 1]

Section 2

Section 2 deletes "401" from present section 701 (e), thus rendering the procedural requirements of that section inapplicable to orders issued upon proposals published under section 401 (b) (1) after enactment of this act.

* * * * * * *

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

[p. 4]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) * * *

* * * * * * *

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue amend, or repeal any regulation contemplated by any of the following sections of this Act: [401,] 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in [p. 5] person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the

ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

[p. 6]

1.12e (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 1060, 83rd Cong., 2d Sess. (1954)

AMENDING SECTIONS 401 AND 701 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO ESTABLISHMENT OF FOOD STANDARDS

MARCH 9 (legislative day, March 1), 1954.—Ordered to be printed

Mr. PURTELL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 6434]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 6434) to amend sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the establishment of food standards, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE OF THE BILL

The main purpose of the bill is to facilitate the making of noncontroversial changes in food standards regulations. The bill is designed to—

(1) Simplify the procedures governing the issuing, amending, or repealing of regulations fixing and establishing definitions and standards of identity, standards of quality, or standards of fill of container for foods as authorized by section 401 of the Federal Food, Drug, and Cosmetic Act by restricting the requirements for the formal type of hearings, as now prescribed in section 701 (e) of that act, to instances where this procedure is desired by a party who would be adversely affected if the regulation, as proposed, were to be effective; and

(2) Enlarge the class of persons who as a matter of right may petition the Secretary to act on a proposal to issue,

amend, or repeal, as the case may be, any such regulation.

The consensus of opinion among all the leading food producers, as well as Food and Drug Administration officials, is that the existing standard-making procedures are slow and cumbersome. The [p. 1] procedural requirements of the present law are unnecessarily burdensome in that they require formal hearings and all that this implies, whether a proposed regulation is controversial or not, with the resultant useless expenditure of time and money by both the Government and the interested industry, even when all are in agreement as to the proposed regulation. Enactment of this bill would provide needed relief from these unnecessary burdens by eliminating the requirement for formal hearings except in instances where such a hearing is desired for the purpose of providing a basis for the judicial review as now provided in the act, should the objecting party find the ultimate regulation still objectionable.

The Commissioner of Food and Drugs, together with counsel representing the interests of leading food producers, appeared before members of the Subcommittee on Health of this committee and strongly urged the early enactment of this legislation. All communications received by the committee concerning this measure have been unanimous in favor of the bill's enactment and the committee knows of no opposition thereto.

The Secretary of Health, Education, and Welfare, whose report follows, as well as the Bureau of the Budget, endorse the bill and recommend its enactment:

Hon. H. ALEXANDER SMITH,
Chairman, Committee on Labor and Public Welfare,
United States Senate, Washington 25, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of August 3, 1953, for a report on H.R. 6434, a bill to amend section 401 and 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the establishment of food standards, as passed by the House of Representatives.

This bill would provide for issuing, amending, or repealing food standards regulations by a procedure comparable to that specified by section 507 (f) of the act for regulations concerning the certification of certain antibiotic drugs. This bill would greatly facilitate noncontroversial changes in food standards regulations. It would eliminate the necessity for public hearings and the establishment of a record of testimony and exhibits where, after due notice, it developed no one opposed the change. A further advantage would be to simplify hearings on regulations containing both controversial and noncontroversial issues by separating and eliminating the noncontroversial.

Experience in the establishment of food standards under authority of section 401 demonstrates that the present procedures are cumbersome and time-consuming, while experience in the promulgation of regulations under section 507 (f) shows that the procedures of that section are simple, equitable, and effective. Amendment of the law to simplify the food standards procedures is highly desirable.

The present law requires the Secretary to hold hearings on proposals to issue, amend, or repeal food standards upon application of an interested industry or substantial portion thereof, stating reasonable grounds therefor. The bill broadens this provision by requiring a hearing on petition of any interested person, stating reasonable grounds. We regard this change as in the interest of fairness and the development of improved technology in food production.

The House of Representatives made minor technical changes from the original House bill, H.R. 5055, that are entirely acceptable to this Department.

This Department endorses this bill and recommends its enactment.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

OVETA CULP HOBBY, *Secretary*.

[p. 2]

Section 2

Section 2 deletes "401" from present section 701 (e), thus rendering the procedural requirements of that section inapplicable to orders issued upon proposals published under section 401 (b) (1) after enactment of this act. [p. 4]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) * * *

* * * * * * *

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: [401,] 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing

[p. 5]

the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

[p. 6]

1.12e (3) CONGRESSIONAL RECORD

1.12e (3) (a) VOL. 991 (1953), July 30: Passed House, p. 10527

[No Relevant Discussion on Pertinent Section]

1.12e (3) (b) VOL. 100 (1954), April 5: Passed Senate, pp. 4556–4557

Mr. PURTELL. Mr. President, the main purpose of the bill is to facilitate the making of noncontroversial changes in food standards regulations. The bill is designed to—

First. Simplify the procedures governing the issuing, amending, or repealing of regulations fixing and establishing definitions and standards of identity, standards of quality, or standards of fill of container for foods as authorized by section 401 of the Federal Food, Drug, and Cosmetic Act by restricting the requirements for the formal type of hearings, as now prescribed in section 701 (e) of that act, to instances where this procedure is desired by a party who would be adversely affected if the regulation, as proposed, were to be effective; and

Second. Enlarge the class of persons who as a matter of right may petition the Secretary to act on a proposal to issue, amend, or repeal, as the case may be, any such regulation.

Actually, enactment of the bill will do away with a great deal of unnecessary work which imposes not only additional cost, but also a loss of time on petitioners and on the Food and Drug administration. No objection at all to the bill has been submitted to the committee; all witnesses who appeared at the hearing were in favor of enactment of the bill.

The Secretary of Health, Education, and Welfare, who has submitted a report on the bill — and the report is printed in the hearings — and various other persons endorse the bill and recommend its enactment.

* * * * *

Mr. GORE. The distinguished Senator from Connecticut has made an able explanation of the bill. Does he consider it in the public interest that formal hearings be waived, even though no direct controversy is involved? Would not it be in the public interest to have available to the public the reasons, formally stated, for such regulations?

Mr. PURTELL. Public hearings are not to be waived, in the sense that there are to be no public hearings, when anyone at all objects to the proposed regulations. The bill provides that time for the filing of objections will be allowed, and then a hearing will be held before any such regulation on the part of the Food and Drug Administration will become binding on the public.

Mr. GORE. Mr. President, will the Senator from Connecticut yield again to me?

Mr. PURTELL. I yield.

Mr. GORE. It may be that our difference of opinion turns on the question of what is and what is not a formal hearing. What kind of hearing would be held in case no controversy were involved?

My point is that a person who applies for a particular decision may well not consider it controversial; but the public interest may not be properly protected—and I stress my use of the word "may" in that connection—unless the public has knowledge of the facts and unless a formal record is made of the facts upon which the regulation is made.

Mr. PURTELL. Of course, any regulation will have to be worked out with the interested parties, and then will be published before it becomes effective.

Mr. BUTLER of Maryland. Mr. President, will the Senator from Connecticut yield to me?

Mr. PURTELL. I yield.

Mr. BUTLER of Maryland. Does the bill contain any provision for recourse to the courts?

Mr. PURTELL. Oh, yes. It does not change existing law in that respect at all.

Mr. GORE. Mr. President, will the Senator from Connecticut explain the difference between the kind of hearing to which he has alluded and the formal type of hearing to which he has made reference?

Mr. PURTELL. I shall be glad to do so. I think perhaps it is better explained in the report, as compared with any extemporaneous explanation I might give.

I read now from the report:

EXPLANATION OF THE BILL BY SECTIONS

SECTION 1

This section amends section 401 of the Federal Food, Drug, and Cosmetic Act by adding a new subsection (b) prescribing the procedure for the promulgation, under such section 401, of regulations fixing and establishing definitions and standards of identity, standards of quality, or standards of fill of container for foods. It does not change the present section 401 except that it will now be designated as section 401 (a).

The procedural provisions of the proposed new subsection (b) are divided into three subdivisions providing respectively, for (1) the initiation of action authorized by section 401 (a) and the issuance of an order upon any published proposal for such action; (2) the filing of objections by any person who will be adversely affected by any order issued under (1); and (3) the formal hearing on objections thus filed, the issuance of an appropriate order following such hearing, and the judicial review, as provided in section 701 (f) and (g), of any challenged order. A more detailed explanation of these provisions follows:

The action contemplated by section 401 (b) (1) includes any action to issue, amend, or repeal any regulation authorized by section 401 (a). This action may be initiated either by publication of a proposal by the Secretary on his own initiative or by filing of a petition by any interested party submitting a proposal to the Secretary for publication.

By allowing "any interested person" to petition for the issuance, amendment, or repeal of any regulation authorized by section 401 (a), the class of members of the food industry who may file the petition as a matter of right has been enlarged. The present law, section 701 (e), provides that a hearing for the purpose of considering issuing, amending, or repealing a regulation authorized by section 401 shall be held "upon application of any interested industry or a substantial portion thereof stating a reasonable ground therefor." This language has been construed as restricting those who may apply for hearings as a matter of right to the basic food manufacturers and food fabricators. This provision has been unnecessarily restrictive on other persons having a legitimate and direct interest in the problems of food standardization. For example, those who manufacture, or have manufactured for them, substances intended for use in processed or fabricated foods may not, under the present law, apply as a matter of right for a hearing to consider the inclusion of their ingredient in a standardized food. This situation will be corrected by this change in language.

The present law, section 701 (e), requires that a showing of "reasonable grounds" be made in support of any application for a hearing. Since the class of persons who may petition for action by the Secretary on their proposal will be substantially enlarged, this requirement, which is being included in the proposed subsection (b) (1), assumes even greater significance and should be retained. Practical administration of the law requires that there be a substantial showing of merit for any proposed action.

Paragraph (2) of the new subsection (b) provides for the filing of objections to any order issued under (1), by any person who will be adversely affected by such order. This refers, of course, to the order acting on a published proposal after a reasonable opportunity has been afforded for presentation of views on the proposed action. The Secretary's action denying a petition filed with him as provided in (1) is not an "order" within the meaning of this term as used in any part of section 401 (b).

The filing of objections will operate to stay the effectiveness of those provisions of the order to which objection is made. In order that all interested parties may be duly apprised of the status of any order after the time for the filing of objections has expired, the Secretary is required to publish a notice in the Federal Register stating which provisions of the proposed order as published are stayed and, when no objections are filed, stating that fact.

Paragraph (3) of the new subsection (b) prescribes the procedure for hearings on the objections filed under paragraph (2) and, by cross reference to section 701 (f) and (g) incorporates these judicial review provisions so that orders issued after hearing, as provided in this paragraph, will remain subject to the same judicial review provisions as those issued under section 401 as at present in effect.

SECTION 2

Section 2 deletes "401" from present section 701 (e), thus rendering the procedural requirements of that section inapplicable to orders issued upon proposals published under section 401 (b)(1) after enactment of this act.

SECTION 3

Section 3 relates to the question of the applicability of the new procedure to matters which may be pending before the Secretary at the time of the enactment of this legislation. It provides that in any case in which prior to the date of the enactment of this legislation, a public hearing has been begun, in accordance with section 701 [p. 4556] (e) of the present law, upon a proposal for issuance, amendment, or repeal of any regulation contemplated by section 401, the provisions of the present law as now in force shall be applicable as though this legislation had not been passed.

The PRESIDING OFFICER. Under the 5-minute rule, the time available to the Senator from Connecticut has expired.

Mr. HENDRICKSON. Mr. President, I ask unanimous consent that the Senator from Connecticut have 2 additional minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. PURTELL. Mr. President, I hope the explanation I have given answers the question of the Senator from Tennessee.

Mr. GORE. Mr. President, will the Senator from Connecticut yield again to me?

Mr. PURTELL. I am glad to yield.

Mr. GORE. From the explanation the Senator from Connecticut has given, it seems clear that in case no objection is filed to an application, no record—that is to say, no stenographic record or no record from the technical, legal standpoint—will be made of the hearing; but if objection is filed in time, a formal hearing will be held.

Mr. PURTELL. That is correct.

Mr. GORE. Mr. President, I must say that I have some doubt as to the advisability of passing the bill. However, in view of the fact that the committee has reported it unanimously, and particularly in view of the consideration which the distinguished senior Senator from Connecticut has given to this bill, and his approval of it, I shall resolve the doubt in favor of his position and withdraw my objection.

Mr. PURTELL. I certainly suggest that if there is any doubt in the Senator's mind we should resolve such doubt.

The PRESIDING OFFICER. (Mr. UPTON in the chair). Is there objection to the present consideration of the bill?

There being no objection, the bill (H. R. 6434) to amend sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the establishment of food standards was considered, ordered to a third reading, read the third time, and passed.

[p. 4557]

1.12f 1956 FEDERAL FOOD, DRUG, AND COSMETIC AMENDMENTS

August 1, 1956, P.L. 84–905, §2, 70 Stat. 919

AN ACT

To amend sections 401 and 701 (e) of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 401 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C., sec. 341) is amended by striking out "(a)" where it appears after "SEC. 401.", and subsection (b) of such section is repealed.

SEC. 2. Section 701 (e) of such Act (21 U.S.C., sec. 371 (e)) is amended to read as follows:

"(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403 (j), 404 (a), 406 (a) or (b), 501 (b), 502 (d) or (h), 504, or 604, of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

"(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

"(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions."

[p. 919]

1.12f (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2623, 84th Cong., 2d Sess. (1956)

AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO SIMPLIFY PROCEDURES GOVERNING THE PRESCRIBING OF REGULATIONS UNDER CERTAIN PROVISIONS OF SUCH ACT

JULY 5, 1956.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. PRIEST from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 9547]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 9547) to amend section 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such act, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Amend the title so as to read:

> A bill to amend sections 401 and 701 (e) of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such Act, and for other purposes.

PURPOSE OF LEGISLATION

The purpose of the bill is to simplify the procedures followed by the Food and Drug Administration in making regulations under certain provisions of the Federal Food, Drug, and Cosmetic Act. The bill would remove in specified situations, where the proposed regulations are not controversial, the mandatory requirement of following formal rulemaking procedures.

The legislation would extend the procedural simplification provisions of Public Law 335, 83d Congress. Public Law 335 was limited in its application to regulations establishing standards of identity, standards of quality, or standards of fill of container, for food products. The experience under Public Law 335 has been [p. 1] so gratifying to both industry and government that all concerned desire to have this simplified procedure apply to all regulatory procedures referred to in section 701 of the Federal Food, Drug, and Cosmetic Act. These include labeling for special dietary foods, tolerances for necessary and unavoidable poisonous and deleterious substances in foods, listing of coal-tar colors which may be certified for use in food, drugs, and cosmetics, and other provisions calling for rulemaking by the Food and Drug Administration.

The procedural requirements of the present law are unnecessarily burdensome. They require formal hearings, whether a proposed regulation is controversial or not. This results in useless expenditures of time and money by both the Government and the interested industry.

The Subcommittee on Health and Science held hearings on this legislation, in the course of which the sponsor of the bill, a representative of the Department of Health, Education, and Welfare, and the chairman of the legislative committee of the food, drug, and cosmetic law section of the New York State Bar Association testified in favor of this bill. The committee knows of no opposition to this legislation.

The reports of the Departments of Health, Education, and Welfare, and Justice, and the Executive Office of the President support the proposed legislation, and read as follows:

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,

June 6, 1956.

HON. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington 25, D. C.

DEAR MR. CHAIRMAN: This is in response to your request of March 1, 1956, for a report on H. R. 9547, a bill to amend section 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedure governing the prescribing of regulations under certain provisions of such act, and for other purposes.

This bill would extend the procedural simplification provisions of Public Law 335, 83d Congress, 2d session, by removing the requirements of formal rulemaking—public hearing, and establishment of a record of testimony and exhibits on which to base a decision—with respect to certain regulations in cases where the regulation, or amendment or repeal of the regulation, is noncontroversial. The regulations concerned are those dealing with labeling for special dietary foods (sec. 403 (j)), emergency permit control (sec. 404), tolerances for necessary and unavoidable poisonous and deleterious substances in foods (sec. 406 (a)), listing of coal-tar colors which may be certified for use in food, drugs and cosmetics (secs. 406 (b), 504, and 604), modification of tests and assays prescribed in official compendia or prescribing tests for official drugs where the compendia have no prescribed tests (sec. 501 (b)), listing of chemical derivatives of habit-forming drugs (sec. 502 (d)), and packaging requirements and labeling precautions for drugs liable to deterioration (sec. 502 (h)).

The bill would greatly facilitate the establishment of regulations insofar as they are noncontroversial. It would also simplify hearings on regulations containing both controversial and noncontroversial issues by separating and [p. 2] eliminating the noncontroversial. On the narrow issues about which there is controversy, any interested person affected by a proposed regulation could, by filing a petition, initiate the formal procedure, including a public hearing, establishment of the public record on which our action would be based, and review of our action in the United States Courts of Appeals. Thus, no substantial rights of any person would be relieved of protection, while government, the public, and industry are relieved of the costs and expenditure of time in holding hearings on points about which all agree.

Experience with Public Law 335, which was limited to regulations establishing standards of identity, quality, and fill of container for food products, has shown that it provides an effective procedure for establishing regulations with a minimum of cost and wasted effort, while at the same time protecting the rights of interested persons.

Your committee's report on H.R. 6434 (which becomes Public Law 335) stated in regard to the proposal to simplify the procedure for food standards issued under section 401 of the act:

"All of the communications received by the committee, including many not a part of the record, and both of the witnesses appearing before the committee, favored the proposed legislation and urged its early enactment. There is no known opposition.

"The consensus of opinion as expressed in these communications and by witnesses appearing before the committee may be fairly stated to be that (*a*) the procedural requirements of the present law are unnecessarily burdensome in that they require formal hearings and all that this implies, whether a proposed regulation is controversial or not, with the resultant useless expenditure of time and money by both the Government and the interested industry, even when all are in agreement as to the proposed regulation; and (*b*) the proposed legislation is favored by them because it should provide the needed relief from these unnecessary burdens by eliminating the requirement for formal hearings except in instances where such a hearing is desired for the purpose of providing a basis for the judicial review as now provided in the act, should the objecting party find the ultimate regulation still objectionable (H. Rept. 934, 83d Cong., 1st sess.)."

We believe that the amendment of section 701 (e) contained in the bill, which makes the simplification effected by Public Law 335 applicable to the procedure for the other regulations governed by section 701 (e), will prove as noncontroversial in its extension to other regulations as was the prior amendment affecting only the food standards procedure.

The existing law is unnecessarily burdensome, and the proposed bill would afford the required relief. We recommend that it be considered favorably by your committee.

We have also prepared and submitted to the President of the Senate an identical draft bill, with a request that it be considered by the appropriate committee of the Senate. A copy of our letter of transmittal of the draft bill is enclosed for your convenience.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

[p. 3]

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington 25, D. C., May 7, 1956.

HON. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington 25, D. C.

MY DEAR MR. CHAIRMAN: This is in reply to your letter of March 1, 1956, requesting the views of the Bureau of the Budget on H.R. 9547, to amend section 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such act, and for other purposes.

This bill would extend to eight additional sections of the Federal Food, Drug, and Cosmetic Act the simplified procedures which have proven workable on a more limited scale under the recently enacted Hale amendment. Under this simplified procedure the holding of a hearing prior to the making or changing of a rule is eliminated as a condition precedent to rulemaking, when the proposed rule is not in controversy. From the point of view of the best utilization of scarce legal and other enforcement personnel of the Food and Drug Administration, this bill would represent a change for the better. Furthermore, the Department of Health, Education, and Welfare asserts that no substantial rights of any persons would be jeopardized by this simplified procedure, inasmuch as the bill provides for the right to a full and impartial hearing upon petition by any person who feels that he would be adversely affected by a proposed rule.

This office would have no objection to the enactment of this measure.

Sincerely yours,

ROBERT E. MERRIAM,
Assistant to the Director.

DEPARTMENT OF JUSTICE,
May 14, 1956.

HON. J. PERCY PRIEST,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H.R. 9547) to amend section 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such act, and for other purposes.

The purpose of the bill would be accomplished by eliminating the present requirement of the Federal Food, Drug, and Cosmetic Act that hearings be conducted in certain cases although no controversy exists.

The act now provides for two separate procedures pertaining to the issuance of regulations. Section 401 (b) relates to regulations pertaining to standards of identity, quality, and fill of containers for food. Section 701 (e) relates to regulations issued pursuant to eight other sections of the act. Under this latter provision a public hearing is required as a condition precedent to the issuance, amendment, or repeal of any regulation covered. Under section 401 (b) a public hearing need be held only when requested by a person adversely affected by a proposed rulemaking action.

[p. 4]

The bill would establish a uniform procedure for the issuance of regulations under the listed sections, and would adopt the provisions of section 401 (b) with respect to public hearings as applicable to all of the sections.

The Department of Justice would have no objection to the enactment of this legislation.

The Bureau of the Budget has advised that there is no objection to the submission of this report.

Sincerely,

WILLIAM P. ROGERS,
Deputy Attorney General.

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTIONS 401 AND 701(e) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401 [(a)] Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided,* That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

[p. 5]

[(b) (1) Any action under subsection (a) for the issuance, amendment, or repeal of any regulation shall be begun by a proposal made (A) by the Secretary of his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

[(2) At any time prior to the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

[(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions. Such order shall be subject to the provisions of section 701 (f) and (g).]

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CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

Sec. 701. (a) * * *

* * * * * * *

[(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon [p. 6] a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.]

(e) (1) Any action for the issuance, amendment, or repeal of any

regulation under section 401, 403 (j), 404 (a), 406 (a) or (b), 501 (b), 502 (d) or (h), 504, or 604, of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an oppportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by

[p. 7]

order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

[p. 8]

1.12f (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 2752, 84th Cong., 2d Sess. (1956)

AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO SIMPLIFY PROCEDURES GOVERNING THE PRESCRIBING OF REGULATIONS UNDER CERTAIN PROVISIONS OF SUCH ACT

JULY 21 (legislative day, July 16), 1956.—Ordered to be printed
Filed under authority of the order of the Senate of July 21 (legislative day, July 16), 1956

Mr. MURRAY, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 9547]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 9547) to amend section 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the prescribing of regulations under certain provisions of such act, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PURPOSE OF LEGISLATION

The purpose of the bill is to simplify the procedures followed by the Food and Drug Administration in making regulations under certain provisions of the Federal Food, Drug, and Cosmetic Act. The bill would remove in specified situations, where the proposed regulations are not controversial, the mandatory requirement of following formal rulemaking procedures.

The legislation would extend the procedural simplification provisions of Public Law 335, 83d Congress. Public Law 335 was limited in its application to regulations establishing standards of identity, standards of quality, or standards of fill of container, for food products. The experience under Public Law 335 has been so gratifying to both industry and government that all concerned desire to have this simplified procedure apply to all regulatory procedures referred to in section 701 of the Federal Food, Drug, and Cosmetic Act. These include labeling for special dietary foods, tolerances for necessary and unavoidable poisonous and deleterious substances in foods, listing of coal-tar colors which may be certified for use in food, drugs, and cosmetics, and other provisions calling [p. 1] for rulemaking by the Food and Drug Administration.

The procedural requirements of the present law are unnecessarily burdensome. They require formal hearings, whether a proposed regulation is controversial or not. This results in useless expenditures of time and money by both the Government and the interested industry.

The Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce in the House of Representatives held hearings on this legislation, in the course of which the sponsor of the bill, a representative of the Department of Health, Education, and Welfare, and the chairman of the legislative committee of the food, drug, and cosmetic law section of the New York State Bar Association testified in favor of this bill.

The committee knows of no opposition to this legislation.

The reports submitted to the House Committee by the Departments of Health, Education, and Welfare, and Justice, and the Executive Office of the President support the proposed legislation, and read as follows:

[p. 2]

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTIONS 401 AND 701 (e) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. [(a)] Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

[(b) (1) Any action under subsection (a) for the issuance, amendment, or repeal of any regulation shall be begun by a proposal made (A) by the Secretary of his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the

[p. 5]

Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

[(2) At any time prior to the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired, the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

[(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions. Such order shall be subject to the provisions of section 701 (f) and (g).]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) * * *

* * * * * * *

[(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less [p. 6] than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the

Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.]

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403 (j), 404 (a), 406 (a) or (b), 501 (b), 502 (d) or (h), 504, or 604, of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested persons may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist

necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

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1.12f (3) CONGRESSIONAL RECORD, VOL. 102 (1956)

1.12f (3) (a) July 16: Passed House, pp. 12911–12912
[No Relevant Discussion on Pertinent Section]

1.12f (3) (b) July 23: Passed Senate, p. 13923
[No Relevant Discussion on Pertinent Section]

1.12g ABBREVIATED RECORDS ON REVIEW ACT

August 28, 1958, P.L. 85–791, §21, 72 Stat. 948

SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended, are amended to read as follows: "A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code."

(b) The first sentence of paragraph (3) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended, is amended to read as follows: "Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently."

[p. 948]

1.12g (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 842, 85th Cong., 1st Sess. (1957)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

JULY 23, 1957.—Ordered to be printed

Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to whom was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill do pass.

The amendments are as follows:

* * * * * * *

[p. 1]

PURPOSE

The purpose of the bill is to permit the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals.

In many instances much of the record made before such agencies is not relevant to the questions actually raised on appeal. This legislation, in permitting an abbreviated record to be transmitted, should result in a substantial saving of time and money without interfering with any of the appellate rights which persons now have under existing law.

[p. 6]

Sections 3 to 33 contain provisions which make changes to present law. For the most part those changes are to conform the present provisions of law to section 2 of the bill and are explained in another part of this report under "Explanation of amendments". The agencies, boards, commissions or offices whose orders are to be reviewable under the statutes proposed to be amended by sections 3 to 34 of the bill are the following:

Section 3.	Federal Trade Commission
Section 4.	Interstate Commerce Commission, Federal Communications Commission, Civil Aeronautics Board, Board of Governors of the Federal Reserve System
Section 5.	Postmaster General
Section 6.	Secretary of Agriculture
Section 7.	Contract Market Commission, Secretary of Agriculture
Section 8.	Secretary of the Treasury
Section 9.	Securities and Exchange Commission
Section 10.	Securities and Exchange Commission
Section 11.	Foreign Trade Zone Board

Section 12. Federal Communications Commission
Section 13. National Labor Relations Board
Section 14. Secretary of the Treasury
Section 15. Securities and Exchange Commission
Section 16. Federal Power Commission
Section 17. Federal Maritime Board; Secretary of Commerce
Section 18. Civil Aeronautics Board
Section 19. Federal Power Commission
Section 20. Secretary of Health, Education, and Welfare, Secretary of Agriculture
Section 21. Secretary of Health, Education, and Welfare
Section 22. Secretary of Labor
Section 23. Railroad Retirement Board
Section 24. Secretary of Agriculture
Section 25. Securities and Exchange Commission
Section 26. Securities and Exchange Commission
Section 27. Public Health Service
Section 28. Secretary of Agriculture
Section 29. Subversive Activities Control Board
Section 30. Detention Review Board
Section 31. Federal Communications Commission, Secretary of Agriculture, Federal Maritime Board, Maritime Administration, Atomic Energy Commission
Section 32. Department of Health, Education, and Welfare
Section 33. Attorney General (Executive Order 10644)
Section 34. Board of Governors of the Federal Reserve System

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5. Section 21 of the bill would amend section 701 (f) of the Federal Food, Drug, and Cosmetic Act to provide in effect that the filing and contents of the administrative record with the court shall be governed by the proposed section 2112 of title 21 United States Code. We believe that, in the interest of uniformity within the Federal Food, Drug, and Cosmetic Act the additional changes contained in section 20 of the bill, above referred to, should also be incorporated in section 21. We therefore suggest that section 21 be changed to read as follows:

"SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 (f)), are amended to read as follows: 'A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code.'

"(b) The first sentence of paragraph (3) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 (f)) is amended to read as follows: 'Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently'."

[p. 21]

SEC. 21. (a) The second and third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: *A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose.* [The summons and petition may be served at any place in the United States.] "The Secretary [promptly upon service of the summons and petition] thereupon shall [certify and] file in the court the

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[transcript] record of proceedings [and the record] on which the Secretary based his order, *as provided in section 2112 of title 28, United States Code.*" (21 U.S.C., sec. 371, Secretary of Health, Education, and Welfare).

(b) The first sentence of paragraph 3 of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: "*Upon the filing of the petition referred to in paragraph (1) of this subsection,* the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently."

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1.12g (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 2129, 85th Cong., 2d Sess. (1958)

AUTHORIZING ABBREVIATED RECORDS IN REVIEWING ADMINISTRATIVE AGENCY PROCEEDINGS

AUGUST 4, 1958.—Ordered to be printed

Mr. EASTLAND, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 6788]

The Committee on the Judiciary, to which was referred the bill (H.R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies by the courts of appeals and the review or enforcement of such orders on the original papers and to make uniform the law relating to the record on review or enforcement of such orders, and for other purposes, having considered the same, reports favorably thereon, without amendment, and recommends that the bill do pass.

PURPOSE

The purpose of the proposed legislation is to save time and expense by permitting the several courts of appeals to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals. If review proceedings have been instituted in two or more courts with respect to the same order, the bill would require the Federal administrative agency involved to file the record in that court in which the proceeding was first instituted, but in the interest of justice and for the convenience of the parties, such court may thereafter transfer the proceedings to another court of appeals.

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STATEMENT

1. ORIGIN AND PRIOR CONSIDERATION

This proposal emanates from the Judicial Conference of the United States. It was submitted to the Congress after substantial consideration by the Committee on Revision of the Laws of the Judicial Conference and the Judicial Conference itself. After submission, it was the subject of a hearing before a subcommittee of the House Committee on the Judiciary on May 17, 1956, and subjected to agency comments. It was thereafter revised and reintroduced and again subjected to review by the administrative agencies. Following this, the Judiciary Committee after adopting several amendments, reported the bill to the House of Representatives, which later approved it.

The bill has been approved in principle by the American Bar Association, and it incorporates a recommendation of the President's Conference on Administrative Procedure. It likewise carries the approval of the Judicial Conference of the United States.

2. DISCUSSION AND SUMMARY

Most of the present statutes which provide for judicial review or enforcement by the courts of appeals of the orders of administrative agencies require that a transcript of the entire record of the proceedings before the agency be prepared by the agency and physically filed with the court. Such a requirement frequently operates to delay court proceedings and to impose upon the agency large and unnecessary expenditures of money and effort. In many types of cases the agency record involves persons other than the petitioner for review. The record may, therefore, be unnecessarily voluminous and much of it irrelevant to the review.

The object of the instant legislation is to eliminate the filing of the entire record except in those instances where it is required for an adequate determination or where the abbreviation of the record would prove more costly than the transmission of the entire record. This objective could have been accomplished by a general statute repealing all inconsistent provisions of the various acts providing for judicial review of agency action. Such a course, however, would have left a residuum of doubt as to whether specific provisions would have been repealed by implication. This legislation avoids that difficulty by direct amendment of the many existing statutes providing for judicial review of administrative determinations and orders.

Many of the statutes providing for the enforcement or review of agency orders provide that the courts of appeals acquire jurisdiction upon the filing of the petition for review. Many others provide however, that jurisdiction is not acquired by the courts until the filing of the transcript of the record. This latter provision has sometimes proved both illogical and unwise—illogical, since it places authority within the Federal agency to delay the acquisition [p. 2] of full jurisdiction by a Federal appellate court; and unwise, since it raises a serious question concerning the extent of the court's authority to make orders relating to the filing of the record or other preliminary orders between the time of filing the petition for review and the time when the record is actually filed. Accordingly, this legislation proposes to amend various statutes to provide that in all cases the reviewing court shall acquire jurisdiction upon the filing of a petition on review. However, the bill further provides that although jurisdiction shall be immediately acquired by the court upon the filing of a petition for review, the existing jurisdiction of agencies, pending filing of the record, is preserved and until such filing the jurisdiction shall be concurrent and shall become exclusive in the appellate court only upon the filing of the record. This provision was added in order to make clear that up to the filing of the record or transcript, an agency may retain jurisdiction in order to permit that agency to entertain motions for additional processes before the administrative agency, such as the modification or setting aside of an order.

This legislation accomplishes its objective of permitting the filing of abbreviated records by adding a new section, section 2112, to title 28, of the United States Code, and amending the several statutes relating to appeals from administrative agencies to bring them into conformity with the provisions of this new section of title 28. The bill seeks to accomplish its purposes in the following ways:

(1) By giving the courts of appeals, with the approval of the Judicial Conference, authority to adopt rules on the subject, which are to be so far as practicable uniform in all courts.

(2) By providing for the abbreviation of the record to include only those materials which are relevant to the issues involved as determined by the rules or special orders of the court or by stipulation of the parties.

(3) By providing in appropriate cases which can be disposed of on the pleadings, such as consent decrees, that no record at all need be filed.

(4) By permitting the entire record to be filed in those cases where the parties find it will be less expensive and time consuming to do so than to select and copy portions of it for filing. The selection of the relevant portions of the record to be printed in the petitioner's appendix can sometimes better be done at the brief-writing stage.

(5) By providing that the courts may permit an agency to file in court merely a list of the materials in the record while retaining in its custody the materials themselves until any such materials are actually needed and sent for by the court.

(6) By authorizing the agency, if it finds it better to do so, to transmit original papers, rather than copies, as the record on review. These are, of course, to be returned to the agency upon the termination of the proceeding, or earlier if needed.

The bill would further accomplish its objectives by amending the various statutes now providing for the review and enforcement of agency orders so as to bring about uniformity in their provisions by—

(7) Providing that the record shall be filed in each case as provided in the new section 2112 of title 28;

[p. 3]

(8) Providing that the jurisdiction of the court of appeals shall attach in all cases upon the filing of the petition for review or enforcement, while preserving the concurrent jurisdiction of the agency, in appropriate cases, until the record is filed; and

(9) Providing that in all cases it shall be the duty of the clerk of the court to transmit to the agency a copy of the petition for review which has been filed with the court.

In addition, the bill meets the problem which is presented when petitions by different aggrieved parties to review the same agency order are filed in different circuits. It does so by providing that the court of appeals in which the first petition is filed shall have exclusive jurisdiction of all the petitions but with power to transfer them all to another court of appeals if the convenience of the parties and the interests of justice so require. At present the agency, by selecting the court in which it files the record, determines which court shall have jurisdiction.

CONCLUSION

With the advent of an increasing number of bureaus and agencies within the Federal Government, the Congress has seen fit to authorize judicial review of the orders of such agencies and bureaus in order to afford maximum protection to the interests of the Government and the individual or corporate litigant. In many cases this review function has been placed upon the Federal courts of appeals, thereby increasing the workload of that part of the Federal court system. Part of that workload involves the perusal of records filed in connection with such appeals. These records are frequently voluminous and are not edited, so as to encompass only information relevant to the points at issue. The reduction of such a record to its pertinent parts, as proposed here, should in most cases serve as an aid to the expedition of appeals from orders of administrative agencies. Thus, adoption of this measure is expected to facilitate the work of the Federal appellate courts. Moreover, this legislation is likewise expected to occasion a saving in time and expense to the Federal Government in its role as litigant. The cost of preparing the transcript in nearly all cases rests with the agency and is, therefore, a charge upon the Federal Treasury. Consequently, any reduction in the size of the record which must be filed could result in reducing the cost of litigation to the Government.

In addition to these considerations, the authority conferred by the bill contains sufficient flexibility to permit an appellate court to adapt its procedures to the exigencies of cases presented to it. Thus, if a litigant, either an indivdiual or an agency, determined that the cause of justice, or considerations of time or expense, require the submission of a full record, that may be done. The purpose of the proposal is expedition, but not expedition at the expense of justice .

The bill was the subject of thorough consideration in the Judicial Conference prior to its submission to the Congress, and since its submission has been reviewed in detail by the administrative agencies. It is also appropriate to note that the agency primarily concerned with litigation involving the Federal Government, the Department of Justice, considers the proposal "a laudible effort

[p. 4]

to eliminate unnecessary expenditures in time and money in the review of agency orders by the courts of appeals." In short, the Department of Justice recommends enactment of the measure.

The acceptance and approval of this bill by the bench and the bar indicates that it may reasonably be calculated to accomplish the worthwhile objective which it is designed to accomplish. Consequently, the committee recommends favorable consideration of the legislation.

Attached to this report is the letter of transmittal of the Administrative Office of United States Court, dated April 5, 1957, and the report of the Department of Justice under date of June 10, 1957, to which reference was made earlier. The other agency reports on the bill are incorporated in House Report No. 842 of the 85th Congress, 1st session. In the interests of brevity they may be considered as having been incorporated by reference in this report.

[p. 5]

SEC. 21. (a) The second the third sentences of paragraph (1) of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: *A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose.* [The summons and petition may be served at any place in the United States.] The Secretary [promptly upon service of the summons and petition] *thereupon* shall [certify and] file in the court the [transcript] *record* of the proceedings [and the record] on which the Secretary based his order, *as provided in section 2112 of title 28, United States Code.*"

(b) The first sentence of paragraph 3 of subsection (f) of section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1055), as amended: "*Upon the filing of the petition referred to in paragraph (1) of this subsection, the* [The] court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently." (21 U.S.C., sec. 371, Secretary of Health, Education, and Welfare.)

[p. 17]

1.12g (3) CONGRESSIONAL RECORD

1.12g (3) (a) VOL. 103 (1957), Aug. 5: Amended and passed House, p. 13620

[No Relevant Discussion on Pertinent Section]

1.12g (3) (b) VOL. 104 (1958), Aug. 14: Passed Senate, p. 17537

ENFORCEMENT OF ORDERS OF ADMINISTRATIVE AGENCIES

The bill (H. R. 6788) to authorize the abbreviation of the record on the review or enforcement of orders of administrative agencies, was announced as next in order.

Mr. HRUSKA. Mr. President, may we have an explanation of the bill?

Mr. EASTLAND. Mr. President, this bill authorizes the several courts of appeals of the United States to adopt rules authorizing the abbreviation of the transcript and other parts of the record made before Federal administrative agencies when the orders of those agencies are to be reviewed by the courts of appeals. Under several existing statutes permitting appeals to the court of appeals from the findings and orders of administrative agencies, it is necessary for the administrative agency to prepare and file the entire record of the proceedings before the administrative agency. This oftentimes results in a voluminous record, much of it not pertinent to the matters under review. Many times, likewise, the record involves other applicants not a party to the appeal.

Under the authority conferred by this bill, the courts of appeals could, by special order or by stipulation of the parties, provide for the filing of only those materials which are relevant to the issues before the court. In such matters the courts of appeals must, of necessity, have some latitude, and this legislation affords them that latitude.

The bill also provides that when petitions are filed in different circuits to review the same agency order, the jurisdiction of all the petitions shall rest with the court of appeals in which the first petition is filed but that court will have authority to transfer such cases to another court of appeals if it appears that the convenience of the parties and the interests of justice would be served. Under existing law the agency, by selecting the court in which it files the record, determines which court shall have jurisdiction.

Information submitted to the committee indicated that the adoption of this legislation would result in the saving of time on the part of the court of appeals. Since it is now incumbent upon the Federal agencies to prepare the record for filing in the courts of appeals, it is also likely that this legislation would result in a saving of time and expense on the part of the Federal administrative agencies.

For these reasons, the committee has recommended that the legislation be favorably considered.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the bill was considered, ordered to a third reading, read the third time, and passed.

[p. 17537]

1.12h 1960 AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

July 12, 1960, P.L. 86-618, Title I, §103(a) (4), 74 Stat. 398

REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "SEC. 406." in such section;

(2) repealing section 504;

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or

[p. 398]

(b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604,"; and (C) inserting the word "or" after "501(b),".

[p. 399]

1.12h (1) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 795, 86th Cong., 1st Sess. (1959)

COLOR ADDITIVE AMENDMENTS OF 1959

AUGUST 21, 1959.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 2197]

The Committee on Labor and Public Welfare, to whom was referred the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

EXPLANATION

S. 2197 is designed to better protect the public health with respect to procedures necessary to assure the safety of color additives in foods, drugs, and cosmetics and to authorize the use of such color additives as have been predetermined to be perfectly safe in the amounts in which they are to be used. The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act with a scientifically sound and uniform system for the listing of color additives of any kind which may be safely used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Under existing law coal-tar colors may not be used in foods, drugs, or cosmetics unless they have been certified by the Food and Drug Administration as harmless and suitable for use. A recent Supreme Court decision has defined the "harmless" principle as meaning harmless regardless of the quantity of the coal-tar color which is being used. Thus, a color must be decertified if any [p. 1] quantity or concentration of the color is harmful, even though in lesser concentrations it may be perfectly safe. Because of this principle, as defined by the Supreme Court, it has been necessary for the Food and Drug Administration to withdraw certification of seven food colors. Seventeen additional colors have been proposed for delisting. The effect of the application of the "harmless" principle in terms of existing law is to cause many of the coal-tar colors widely used in industry to be no longer available, and the number of colors withdrawn will eventually seriously handicap manufacturers of foods, drugs, and cosmetics in the production of products in the manner that is customary and usual.

Many food industries find themselves seriously affected by the delisting of colors. If additional proposed delistings are accomplished, similar effect is faced by drug and cosmetic industries. The very existence of many products depends upon the use of suitable color.

This legislation is necessary, because it will give the Secretary of Health, Education, and Welfare a flexibility, which he does not have under the present law, to certify coal-tar colors within tolerance limits which he determines are safe.

Two amendments to the bill as originally introduced were adopted by the committee. Both amendments were developed cooperatively by the committee staff, representatives of the industries concerned, and representatives of the Food and Drug Administration.

Both have been declared acceptable by the Administration and by industry. Their objectives are, first, to permit those additives found "safe" by the Secretary under the procedures set forth in the Food Additives Amendments Act of 1958 to be considered "safe" when used as color additives, and secondly, to relieve the Administration from the obligation of requiring the use of certain analytical methods, when, in its opinion, they are not needed.

The bill as amended has the endorsement of the Administration and of the following business groups which have concerned themselves with the legislation: The Certified Color Industry Committee, the Toilet Goods Association, the National Association of Margarine Manufacturers, the International Association of Ice Cream Manufacturers, the Grocery Manufacturers of America, and the National Confectioners Association.

S. 2197 was introduced at the request of the Department of Health, Education, and Welfare with the approval of the Bureau of the Budget.

DEPARTMENTAL COMMENT

Set forth below are, first, the letter of transmittal from Arthur S. Flemming, Secretary, Department of Health, Education and Welfare, requesting the introduction of the legislation and setting forth the principal reasons which give rise to the need for immediate action in this field, and second, letters dated August 7 and August 12, 1959, from Elliot L. Richardson, Assistant Secretary, Department of Health, Education, and Welfare, expressing approval of the committee amendments.

* * * * * * *

[p. 2]

[SECTION-BY-SECTION ANALYSIS]

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

[p. 15]

* * * * * * *

[Section 706]

Procedure for Issuance, Amendment, or Repeal of Regulations

(d) The provisions of section 701 (e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsections (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f)(2); and

(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

Fees

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Exemptions

(f) The Secretary shall by regulation (issued without regard to subsection (d) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

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1.12h (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960)

COLOR ADDITIVE AMENDMENTS OF 1960

JUNE 7, 1960.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7624]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments, as they appear in the reported bill, are as follows:

[p. 1]

PURPOSE OF LEGISLATION

The purpose of this bill is to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerances, under which such additives may be safely used.

GENERAL SUMMARY

The committee bill—

(1) takes "color additives" out of the scope of the Food Additives Amendment of 1958;

(2) repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604);

(3) enacts new, integrated provisions for the separate listing of suitable "color additives," safe for use in food, drugs,

or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted;

(4) provides for the certification (or exemption from certification) of listed color additives for such permitted uses;

(5) adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and

(6) contains transitional provisions for commercially established colors.

HEARINGS

Extensive hearings were held by the committee on this legislation in January, February, March, and May 1960 and a large number of witnesses were heard. The committee also heard from a distinguished group of scientific experts, selected by the President of the National Academy of Sciences, which discussed the scientific problems involved in this legislation, with special emphasis on the Delaney anticancer clause.

[p. 6]

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

[p. 24]

[CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

[SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act; notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

[p. 55]

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406 [(a) or (b)], 501(b), *or* 502 (d) or (h), [504, or 604,] of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the

time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

[p. 6]

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any,

for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

* * * * * * *

[COST OF CERTIFICATION OF COAL-TAR COLORS

[SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.]

[p. 7]

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C., 109, will, of course, apply to these repeals.

[p. 70]

1.12h (3) CONGRESSIONAL RECORD

1.12h (3) (a) VOL. 105 (1959), Aug. 24: Amended and passed Senate p. 16777

[No Relevant Discussion on Pertinent Section]

1.12h (3) (b) VOL. 106 (1960), June 25: Amended and passed House, pp. 14334, 14373, 14376

[No Relevant Discussion on Pertinent Section]

1.12h (3) (c) VOL. 106 (1960), June 30: Senate concurs in House amendments, p. 15133

[No Relevant Discussion on Pertinent Section]

1.13 PENALTIES—VIOLATION OF SECTION 331 OF THIS TITLE

21 U.S.C. §333(c) (1970)

[Referred to in 21 U.S.C. §346a (n)]

PENALTIES—VIOLATION OF SECTION 331 OF THIS TITLE

§ 333.

* * * * * * *

Exceptions in certain cases of good faith, etc.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor (b) (1) of this title is applicable, if the delivery of proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i) (2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i) (3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

June 25, 1938, c. 675, § 303, 52 Stat. 1043; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237, Oct. 26, 1951, c. 578, § 2, 65 Stat. 649; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub.L. 86-618, Title I, § 105(b), 74 Stat. 403; and amended July 15, 1965, Pub.L. 89-74, §§ 7, 9(d), 79 Stat. 233, 235; Oct. 24, 1968, Pub.L. 90-639, § 3, 82 Stat. 1361; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(b), 84 Stat. 1281.

1.13a FEDERAL FOOD, DRUG, AND COSMETIC ACT PENALTIES

June 25, 1938, P.L. 75-717, §303, 52 Stat. 1043

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine;

but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person estab-
[p. 1043]
lishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.
[p. 1044]

1.13a (1) SENATE COMMITTEE ON COMMERCE

S. REP. No. 91, 75th Cong., 1st Sess. (1937)

FOODS, DRUGS, AND COSMETICS

FEBRUARY 15, 1937.—Ordered to be printed

Mr. COPELAND, from the Committee on Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Commerce, to whom was referred the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics, in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having considered the same, report thereon with certain amendments, and as so amended, recommend that the bill do pass. The amendments are incorporated in the bill as reported.

This bill has been prepared with three basic principles in mind: First, it must not weaken the existing laws; second, it must strengthen and extend that law's protection of the consumer; and third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.

[p. 1]

Technical, innocent violations of this bill will frequently arise. Overzealous enforcement officers could cause honest business untold damage and annoyance. The bill, therefore, limits the enforcement officers in the drastic power of unlimited seizure to cases of adulteration and those cases of misbranding where, in the public interest, the power should be exercised. In addition, this bill increases the criminal penalties for adulteration and misbranding over those in the existing law, and adds injunction, temporary and permanent, as a means of prohibiting adulteration and misbranding. The existing law does not have such a provision.

[p. 4]

The only other change of consequence in the seizure provision is that when seizures have been made the trial may be held in a district of reasonable proximity to the claimant's place of business. Nothing is claimed for this provision except that it is fair. Goods must be seized wherever found. But, there is no reason why a claimant for the goods, who perhaps may reside across the continent, should be compelled to cross the country to try the case.

A summary of the principal respects in which this bill increases the scope of the old law and affords the public greater protection follows:

* * * * * * *

[p. 5]

GENERAL

20. Prohibits the use of poisonous containers for food, drugs, and cosmetics.
21. Requires that food, drugs, and cosmetics be prepared and handled under conditions of reasonable cleanliness.
22. Forbids the use of uncertified and impure coal-tar colors in food, drugs, and cosmetics.
23. Prohibits slack-filling and the use of deceptive containers for food and drugs.
24. Provides for factory inspection and the procurement of records needed to prove Federal jurisdiction.
25. Provides increased penalties for violations.
26. Authorizes the Federal courts to enjoin violations.

[p. 6]

1.13a (2) SENATE COMMITTEE ON COMMERCE

S. REP. No. 152, 75th Cong., 1st Sess. (1937)

FOODS, DRUGS, AND COSMETICS

MARCH 8, 1937.—Ordered to be printed

Mr. COPELAND, from the Committee on Commerce, submitted, in lieu of Senate Report No. 91, the following

AMENDED REPORT

[To accompany S. 5]

The Committee on Commerce, to whom was referred the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics, in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, and which was heretofore reported with certain amendments, submit herewith an amended report and recommend that the bill, as amended, do pass. The amendments are incorporated in the bill as reported.

[p. 1]

Technical, innocent violations of this bill will frequently arise. Overzealous enforcement officers could cause honest business untold damage and annoyance. The bill, therefore, limits the enforcement officers in the drastic power of unlimited seizure to cases of adulteration and those cases of misbranding where, in the public interest, the power should be exercised. In addition, this bill increases the criminal penalties for adulteration and misbranding over those in the existing law, and adds injunction, temporary and permanent, as a means of prohibiting adulteration and misbranding. The existing law does not have such a provision.

[p. 4]

FOODS, DRUGS, AND COSMETICS

The only other change of consequence in the seizure provision is that when seizures have been made the trial may be held in a district of reasonable proximity to the claimant's place of business. Nothing is claimed for this provision except that it is fair. Goods must be seized wherever found. But, there is no reason why a claimant for the goods, who perhaps may reside across the continent, should be compelled to cross the country to try the case.

A summary of the principal respects in which this bill increases the scope of the old law and affords the public greater protection follows:

* * * * * * *

[p. 5]

GENERAL

20. Prohibits the use of poisonous containers for food, drugs, and cosmetics.

21. Requires that food, drugs, and cosmetics be prepared and handled under conditions of reasonable cleanliness.

22. Forbids the use of uncertified and impure coal-tar colors in food, drugs, and cosmetics.

23. Prohibits slack-filling and the use of deceptive containers for food and drugs.

24. Provides for factory inspection and the procurement of records needed to prove Federal jurisdiction.

25. Provides increased penalties for violations.

26. Authorizes the Federal courts to enjoin violations.

[p. 6]

1.13a (3) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 2139, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

APRIL 14, 1938.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. LEA, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Interstate and Foreign Commerce, to whom was referred the act (S. 5) to prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, report favorably thereon with an amendment and recommend that the act do pass.

The committee amendment strikes out all of the Senate bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

The act herewith reported is the culmination of more than 5 years of study by your committee.

GENERAL PURPOSES

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U. S. C., title 21, secs. 1–15). That act is popularly known as the Wiley pure-food law, because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions.

[p. 1]

Section 303 increases substantially the criminal penalties of the present law which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business. Appropriate exemptions are provided for dealers who innocently receive and distribute illegal goods.

[p. 4]

Further opportunity for review of a regulation placed in effect by the Secretary will occur in criminal, injunction, libel for condemnation, exclusion of imports, or other proceedings instituted by the Government under the bill, in which the defendant is charged with violating the regulation (see secs. 302, 303, 304, and 801). If, through prior review proceedings, there has been a final determination of the validity of the regulation or order in question by the Supreme Court of the United States, or the circuit court of appeals for the particular circuit, then the question of validity would likely have become stare decisis. If, however, this is not the case, the validity of the regulation or order could be inquired into and determined in such criminal, injunction, libel for condemnation, exclusion of imports, or other proceedings.

[p. 11]

1.13a (4) COMMITTEE OF CONFERENCE

H.R. REP. No. 2716, 75th Cong., 3rd Sess. (1938)

FOOD, DRUG, AND COSMETIC ACT

JUNE 11, 1938.—Ordered to be printed

Mr. LEA, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 5]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 5) to prevent the adulteration, misbranding, and false advertisement of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

[p. 1]

Penalties

Sec. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded,

[p. 4]

within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.

[p. 5]

1.13a (5) CONGRESSIONAL RECORD

1.13a (5) (a) VOL. 81 (1937), March 9: Amended and passed Senate, p. 2005

The next amendment of the committee was, in section 5, paragraph (a), on page 11, line 24, after the word "subdivisions", to strike out "(1), (2), (3), (4), (6), (7), or (8)" and to insert in lieu thereof "(a), (b), (c), (d), (f), (g), or (h)", so as to make the subdivision read:

> CRIMINAL
>
> SEC 5. (a) Any person who violates any of the provisions of subdivisions (a), (b), (c), (d), (f), (g), or (h) of section 3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than 1 year or a fine of not more than $1,000, or both such imprisonment and fine; and for a second or subsequent offense imprisonment for not more than 2 years, or a fine of not more than $5,000, or both such imprisonment and fine.

The amendment was agreed to.

[p. 2005]

1.13a (5) (b) VOL. 83 (1938), June 1: Amended and passed House, p. 7903

[No Relevant Discussion on Pertinent Section]

1.13a (5) (c) VOL. 83 (1938), June 10: Senate agrees to conference report, pp. 8732

[No Relevant Discussion on Pertinent Section]

1.13a (5) (d) VOL. 83 (1938), June 13: House agrees to conference report, pp. 9088–9089

[No Relevant Discussion on Pertinent Section]

1.13b 1940 REORGANIZATION PLAN IV, §12, 54 STAT. 1237

SEC. 12. *Transfer of Food and Drug Administration*—The Food and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval Stores Act, are transferred to the Federal Security Agency and shall be administered under the direction and supervision of the Federal Security Administrator. The Chief of the Food and Drug Administration shall hereafter be known as the Commissioner of Food and Drugs.

[p. 1237]

1.13c 1951 AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

October 26, 1951, P.L. 82–215, §2, 65 Stat. 649

SEC. 2. Subsection (c) of section 303 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by striking out the period at the end of clause (3) and inserting in lieu thereof a semicolon and the following: "or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article."

[p. 649]

1.13c (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 700, 82nd Cong., 1st Sess. (1951)

AMENDING SECTION 503 (b) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

JULY 16, 1951.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WILLIAMS of Mississippi, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H. R. 3298]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert the following:

That subsection (b) of section 503 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended to read as follows:

"(b) (1) A drug intended for use by man which—

"(A) is a habit-forming drug to which section 502 (d) applies; or

"(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, has been determined by the Administrator, on the basis of opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug (and, where a public hearing is required by paragraph (5), on the basis of evidence adduced at such hearing by such experts), to be safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug; or

"(C) is limited by an effective application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

"(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and [p. 1] (3), (k), and (l) and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient or to a drug dispensed in violation of paragraph (1) of this subsection.

"(3) The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

"(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription'. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence or any other statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner is prohibited.

"(5) Any interested person may file with the Administrator a petition proposing the making of a determination, or the modification of a determination made or proposed to be made, by the Administrator pursuant to subparagraph (B) of paragraph (1). The filing of a petition for the purpose of opposing a proposed determination that a drug is one to which such subparagraph (B) applies shall stay the operation of paragraph (1) with respect to such drug until a petition for judicial review can be filed and interim relief sought under section 10 (d) of the Administrative Procedure Act. The petition shall set forth in general terms the proposal contained therein, and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal made in the petition and shall give to all interested persons a reasonable opportunity to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action on the proposal. At any time prior to the thirtieth day after such action is made public, any interested person may file with the Administrator objections to such action, specifying with particularity the changes proposed, stating reasonable grounds therefor, and requesting a public hearing for the taking of evidence of experts who are qualified by scientific training and experience to testify on the question of whether the drug in question is safe and efficacious for use only after professional diagnosis by, or under the supervision of, a practitioner licensed by law to administer such drug. The Administrator shall thereupon, after appropriate notice, hold such public hearing. As soon as practicable after the hearing, the Administrator shall make his determination and issue an appropriate order. The Administrator shall make his order only after a review of the whole record and in accordance with the reliable, probative, and substantial evidence, and shall make detailed findings of the facts on which he based his order. Such order shall be subject to judicial review in accordance with the provisions of section 701 (f) and (g).

"(6) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U. S. C. 3220), or to marijuana as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 3238 (b))."

SEC. 2. The provisions of this act shall take effect six months after the date of its enactment.

WHAT THE BILL DOES

This bill amends the Federal Food, Drug, and Cosmetic Act to accomplish two broad objectives:

(1) To strengthen the protection of the public health against dangerous abuses in the sale of potent prescription drugs;

(2) To relieve retail druggists and the public from burdensome and unnecessary restrictions on the dispensing of drugs which may be safely used without supervision by a physician.

[p. 2]

The bill does this by placing in the Federal Food, Drug, and Cosmetic Act express provisions which will eliminate confusion and dissatisfaction which exist under the present rather general provisions dealing with the labeling and dispensing of drugs which may be sold only on prescription and drugs which may be sold over the counter.

The bill, as amended, is designed to solve these labeling and dispensing problems in the following ways:

1. By providing for a clear-cut method of distinguishing between "prescription" drugs (that is, drugs which are not suitable for self-medication because they should be used only under the supervision of a physician, and which therefore should be dispensed only on prescription) and "over-the-counter" drugs (that is, drugs which are suitable for self-medication, and which therefore should be permitted to be dispensed freely "over-the-counter"), and by requiring that drugs be so labeled as to indicate to the retail drug-

gist and to the general public into which of these two classes they fall.

> Under the present law, and the regulations issued thereunder, the initial responsibility is upon the manufacturer to decide whether his drug is unsuitable for self-medication and therefore must be labeled with a caution legend (that is, a warning that the drug in question may be dispensed only by or on prescription of a physician) and may be sold only on prescription, or whether his drug is suitable for self-medication and therefore must be labeled with adequate directions for use and may be sold freely over the counter. Lack of uniformity among manufacturers in interpreting the present law and regulations has led to great confusion in the labeling of drugs for prescription sale and for over-the-counter sale.

2. By expressly setting forth in the statute the restrictions applicable to the dispensing of "prescription" drugs.

> At present the restrictions on dispensing "prescription" drugs are not specifically stated in the statute. As hereafter explained, they result from conditions which have been imposed by the Federal Security Administrator in connection with certain exemptions which he is authorized to grant under the present law.

3. By authorizing the filling and refilling of telephone prescriptions under appropriate safeguards.

> The present law recognizes written and signed prescriptions only, in complete disregard of the need for the use of the telephone in prescribing medicines.

4. By specifying in detail the conditions under which pharmacists may refill prescriptions.

> Under the present law no prescription may be lawfully refilled unless refilling is specifically authorized in writing by the prescribing physician. This makes it unlawful for the pharmacist to refill prescriptions without written authorization even for drugs which are suitable for self-medication. The bill would permit the refilling of prescriptions for such drugs without authorization from the physician. However, in the case of dangerous drugs, habit-forming drugs, and new drugs which are limited to use under medical supervision, it would prohibit refilling unless the prescribing physician specifically authorizes the refill.

[p. 3]

CHANGES IN EXISTING LAW

In compliance with paragraph 2a of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTION 503 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packing requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

[(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

> [(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and
>
> [(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).]

(b) A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription, or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient. If the drug is intended for use by man and—

> *(1) is a habit-forming drug subject to the regulations prescribed under section 502 (d);*
>
> *(2) has been found by the Administrator, after investigation and opportunity for public hearing, to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law;*
>
> [p. 18]
>
> *(3) if an effective application under section 505 limits it to use under the professional supervision of a practitioner licensed by law, such exemption shall apply only if such drug is dispensed upon a written prescription of a practitioner licensed by law to administer such drug or upon an oral prescription of such practitioner which is reduced to writing and filed by the pharmacist, or is dispensed by refilling a prescription*

if such refilling is authorized by the prescriber in the original prescription or by oral order and such order is reduced to writing and filed by the pharmacist.

The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the provision of this subsection when such requirements are not necessary for the protection of the public health.

A drug which is subject to clause (1), (2), or (3) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits sale or dispensing without prescription".

The act of dispensing a drug contrary to the provisions of this subsection shall be deemed to be an act which results in the drug's being misbranded while held for sale.

Any interested person may file with the Administrator a petition proposing the addition to, or deletion from, the list of drugs promulgated by the Administrator in accordance with clause (2) hereof. Such petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections.

An order so issued by the Administrator may, within ninety days after its issuance, be appealed by any interested person in accordance with the provisions prescribed in section 701 (f) and (g) of this Act, except that an appeal from the Administrator's order issued hereunder shall be in the nature of a trial de novo, without presumptions in favor of either party to such appeal.

The provisions of this section of the Act shall not be applicable to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marijuana as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 328 (b)).

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APRIL 30, 1951.

HON. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H. R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 352) sets forth the various circumstances under which drugs and devices will be deemed to be misbranded. Section 503 (b) (21 U. S. C. 353 (b)) specifies certain exemptions with respect to drugs dispensed on written prescriptions.

The bill would amend section 503 (b) so as to provide that a drug dispensed by filling or refilling a written or oral prescription shall be exempt from the requirements of section 502, except with respect to certain packaging requirements and those provisions of the section which provide that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular or if it is an imitation of another drug or if it is offered for sale under the name of another drug, and except with respect to the provisions of the act dealing with insulin and the various antibiotics covered by the statute. The measure provides, however, that such exemption shall prevail only if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

Separate provision is made if the drug is intended for use by man, and is (1) a habit-forming drug subject to the regulations prescribed under section 502 (d) (21 U. S. C. 352 (d)), or (2) has been found by the Federal Security Administrator to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law, or (3) if an effective new drug application under section 505 (21 U. S. C. 355) limits it to use under the professional supervision of a licensed practitioner. In such event the exemption is to apply only if the drug is dispensed upon a written prescription or upon an oral prescription which is reduced to writing and filed by the pharmacist, or is dispensed by refilling a prescription if such reflling is authorized by the prescriber in the original prescription or the oral order and such order is reduced to writing and filed by the pharmacist. A drug which falls within the three categories mentioned immediately above will be misbranded if at any time prior to its being dispensed its label fails to bear the statement "Caution: Federal law prohibits sale or dispensing without prescription."

The bill also provides that the act of dispensing the drug contrary to the provisions of the bill shall be deemed to be an act which results in the drug's being misbranded while held for sale. This would insert into the Federal Food, Drug, and Cosmetic Act the theory, based on regulations, pursuant to which the Food and Drug Administration has recommended prosecution of druggists who sell, without prescriptions, drugs bearing the so-called pres- [p. 22] cription legend and which have not been removed from the immediate containers in which they were shipped in interstate commerce. Such a sale by a druggist would be in violation of section 301 (k) (21 U. S. C. 331 (k)).

The bill also provides a procedure whereby any interested person may file a petition with the Federal Security Administrator proposing the addition to or deletion from the list of drugs found to be unsafe or ineffective for use in accordance with clause (2) of section 503 (b). Upon the filing of such a petition, the Administrator is required to give public notice of the proposal and a hearing thereon, and as soon as practicable thereafter shall make public his action upon such proposal. Any interested person may file objections to such action and request a public hearing upon such objections. The Administrator shall thereupon after due notice hold such public hearing and as soon as practicable thereafter by order make public his action on such objections. The order of the Administrator may within 90 days after its issuance be appealed to the court of appeals in accordance with the provisions prescribed in section 701 (f) and (g) of the Act (21 U. S. C. 371 (f) and (g)), except that such appeal shall be in the nature of a trial de novo without presumptions in favor of either party to such appeal.

The bill also provides that its provisions shall not apply to drugs now included or which may hereafter be included within the classification stated in section 3220 of the Internal Revenue Code or to marijuana as defined in section 3238 (b) thereof.

Whether the bill should be enacted involves a question of policy concerning which this Department prefers not to make any recommendation. There are certain features of the measure, however, concerning which the committee may wish to give further consideration.

The bill provides for two public hearings in connection with a proposal for the addition to or deletion from the list of drugs found to be unsafe in accordance with the provisions of clause 2. A public hearing is provided for on the original proposal, and again provided for in connection with objections to the action of the Administrator upon the proposal. It would seem that one public hearing on the original proposal would be sufficient.

The bill also provides for an appeal from the order of the Administrator. It is assumed that the order referred to is that made after the public hearing on the objections to the previous action of the Administrator. The review proceeding is to be in accordance with the provisions of section 701 (f) and (g) of the act, except that the appeal shall be in the nature of a trial de novo. It will be noted, however, that the review proceedings in section 701 are confined to questions of law. The court is given jurisdiction to affirm the order complained of or to set it aside in whole or in part. If the order refuses to issue, amend, or repeal a regulation and such order is not in accordance with law, the court shall by its judgment order the Administrator to take action with respect to the matter, in accordance with law. In a de novo proceeding the court ordinarily has the power and function to make its own findings and judgment. Such a trial contemplates not only the record before the Administrator but the testimony of additional witnesses if desired. No such procedure is contemplated under section 701. The provision for a trial de novo would be incompatible with the review procedure provided for and leaves an ambiguity and doubt as to what the function of the appellate court would be. In addition, such a proceeding would appear to make the appellate court a revising agency and its action in the nature of an administrative decision. A question arises as to whether such a function is within the judicial power conferred upon Federal courts by the Constitution. Compare *Radio Commission v. General Electric Co.* (281 U. S. 464).

It might be desirable to consider the question of review in connection with the action of the Administrator in designating unsafe drugs under clause (2). It is believed that a review from such a determination in accordance with the procedure in section 701, would fully protect the rights of any person adversely affected since the Supreme Court has recently held that in considering the question of whether an order of this nature is supported by substantial evidence, the appellate court shall review the whole record.

The Director of the Bureau of the Budget has advised that there is no objection to the submission of this report.

Yours sincerely,

PEYTON FORD,
Deputy Attorney General.

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1.13c (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 946, 82nd Cong., 1st Sess. (1951)

AMENDING SECTIONS 303 (C) AND 503 (B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

OCTOBER 12 (legislative day, OCTOBER 1), 1951.—Ordered to be printed

Mr. HUMPHREY, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H. R. 3298]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act, as amended, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

The amendments are as follows:

(1) On page 3, line 5, strike out the words "or otherwise without examination of the patient" and insert in lieu thereof a comma.

(2) On page 3, lines 19–22, strike out the words "or any other statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner is prohibited."

(3) On page 4, between lines 5 and 6, insert a new section 2, to read as follows:

> SEC. 2. Subsection (c) of section 303 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting before the period a semicolon and the following: "or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article."

(4) On page 4, line 6, strike out the figure "2" and insert in lieu thereof the figure "3."

INTRODUCTION

This bill amends the Federal Food, Drug, and Cosmetic Act to deal more directly and realistically with the labeling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners. It has a twofold objective: (1) to protect the public from abuses in the sale of potent prescription drugs; and (2) to [p. 1] relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician. The committee believes that the bill, as amended, will serve to eliminate much confusion and dissatisfaction caused by ambiguities in the present provisions of the act, and will benefit drug manufacturers, retail druggists, medical practitioners, and the public.

In its consideration of this bill, the Committee has had the benefit of careful study of its provisions by its standing Subcommittee on Health. The subcommittee carefully and thoroughly explored the need for such legislation at this time, and examined the manner in which the provisions of the bill are adapted to deal with the serious problems which have been shown to exist in connection with the labeling and dispensing of both "prescription" and "over-the-counter" drugs. Hearings on the bill were held before the subcommittee from September 11 through September 13, 1951. Favorable action on the bill was urged at the hearing by the Federal Security Administrator and by the Food and Drug Administration, the agency of the Government that administers and enforces the Federal Food, Drug, and Cosmetic Act. In addition, virtually all segments of the drug industry, including the principal associations of drug manufacturers, the retail druggists, and the licensed pharmacists were represented at the hearing and submitted testimony which clearly shows that this bill is necessary legislation and will do much to make the Act a fairer and more effective instrument for protecting the public against abuses in the labeling and dispensing of drugs. A representative of the American Medical Association testified at the hearing in support of the bill.

The hearing held before the subcommittee developed the fact that while there was virtually unanimity of opinion of those who testified as to the need for basic changes in the law governing the labeling and dispensing of "prescription" drugs, there were two principal issues in controversy.

1. The first area of controversy was over a proposal to authorize the Federal Security Administrator to list by name or class the "dangerous" drugs that may be sold only on prescription. The subcommittee had before it for consideration at the time of the hearing, not only this bill, which has been passed by the House of Representatives, but also the companion Senate bill (S. 1186), and amendments in the nature of a substitute therefor, introduced by

Senator Humphrey. The principal difference between the bill as passed by the House of Representatives and Senator Humphrey's amendments in the nature of a substitute, had to do with the requirement under which, as part of the definition of so-called dangerous drugs, an administrative determination would have been necessary thus to classify a drug. The amendments in the nature of a substitute for S. 1186 also set forth detailed procedures, including administrative hearings to be followed in connection with the making of administrative determinations referred to, together with provisions for judicial review of such determinations.

Prior to the hearing, the provisions for administrative listing of so-called dangerous drugs were vigorously supported by the National Association of Retail Druggists, and equally vigorously opposed by the several associations of drug manufacturers, including the American Pharmaceutical Manufacturers' Association, the [p. 2] American Drug Manufacturers Association, and the Proprietary Association. At the hearing, however, a statement was submitted on behalf of all four of these associations, indicating an agreement on their part that the controversial provisions for administrative listing of so-called dangerous drugs might be eliminated. The four associations, at the same time, proposed two new amendments to the bill. This agreement had the effect of eliminating one of the principal areas of controversy, particularly in view of the fact that the subcommittee was assured by the Food and Drug Administration and the Federal Security Administrator that the bill, while not in their view the best solution, would be workable in the form proposed under the agreement. The subcommittee recommended to the Committee on Labor and Public Welfare, therefore, that the provisions of the House bill which omit the administrative listing provisions, rather than the provisions of the amendments in the nature of a substitute for S. 1186 which include such provisions, be favorably reported to the Senate. The subcommittee further recommended, in reporting favorably on the House bill, that the bill be amended to include the two amendments proposed by the associations of retail druggists and drug manufacturers under the agreement referred to above. The intent and effect of these amendments are discussed hereafter in this report.

2. The other principal area of controversy which developed at the hearing arose with respect to certain language of the bill which was objected to by the representative of a firm engaged in selling through the mail to epileptic patients living throughout the United States a medication comprised principally of phenobarbital. Al-

though the language in question was included in the legislation as originally introduced in both the House of Representatives and the Senate, in the bill as reported to the House of Representatives by the House Interstate and Foreign Commerce Committee and in the bill as passed in the House of Representatives, no issue had been raised concerning this language prior to the hearing before the subcommittee. The subcommittee, however, felt that the language might safely be omitted from the bill. Accordingly, it proposed, and the committee recommends, that this language be stricken. The effect of this amendment is discussed elsewhere in this report.

WHAT THE BILL DOES

As has been pointed out, the bill amends the Federal Food, Drug, and Cosmetic Act so that its provisions will be better adapted to deal realistically with the labeling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners. Its provisions are remedial in the sense that they are intended to protect the public from abuses in the sale of potent prescription medicines. They will also relieve retail pharmacists of unnecessary restrictions on the dispensing of drugs that are safe for use without medical supervision.

Prescription drugs

The bill provides a statutory definition of prescription drugs; it expressly forbids their sale without a prescription; it specifies how they are to be labeled both at the time of interstate shipment and at the time of ultimate dispensing; and it prohibits unauthorized refilling of prescriptions for them.

[p. 3]

There are three classes of drugs covered by the statutory definition. The first includes the habit-forming drugs subject to section 502 (d) of the present statute. These are such drugs as the barbiturates. The third class includes all new drugs restricted to prescription sale by effective new-drug applications under section 505 of the present statute. There is no controversy whatever about these two classes. The second class includes any drug which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs."

This definition of so-called dangerous drugs is contained in paragraph (b) (1) (B) of the bill. It is substantially the same as the administrative definition now contained in the regulations issued by the Federal Security Administrator under the provisions of the

Federal Food, Drug, and Cosmetic Act. The proposed definition, however, omits the reference to "efficacious" for use, as well as "safe" for use, without the supervision of a medical practitioner in order to be eligible for over-the-counter sale. This omission is not intended to mean that the only matter to be considered in applying the definition is whether or not a particular drug is poisonous.

The word "safe," as used in the definition, is intended to have its ordinary meaning. For example, nontoxic drugs like quinidine sulfate, intended for heart disease, or penicillin, for infections, are not safe for self-medication because their unsupervised use may indirectly cause injury or death. The language of the definition clearly shows that toxicity is only one factor to be considered by the courts in determining whether a particular drug is safe for use without medical supervision. The definition requires the court to consider also other potentialities for harmful effect, the method by which the drug is used, and the collateral measures that may be necessary in order to use the drug safely. When this language is given judicial interpretation consistent with the over-all purpose of the Federal Food, Drug, and Cosmetic Act to protect the public health it will effectively restrict to prescription sale all drugs that require professional supervison for their use.

In order to give this general definition a more precise meaning so that it may be applied with greater uniformity by the drug trade the Administrator can exercise the authority he has under section 701 (a) of the Federal Food, Drug, and Cosmetic Act to issue interpretative regulations. It is to be understood that the inclusion of the statutory definition does not, of course, in any way derogate from the Administrator's authority to interpret and enforce the definition through the issuance of any regulations necessary or appropriate to protect the public from indiscriminate dispensing of drugs over the counter when they may be unsafe for use without the supervision of a practitioner licensed by law to administer such drugs.

As previously stated, the committee considered S. 1186 together with H. R. 3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing is not necessary at this time. It was felt that [p. 4] the statutory definition, together with the authority to make interpretative regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan. If the present confusion is not ended by this legislation it will then be time enough to consider the need for the administrative listing approach.

All drugs covered by the three classifications of prescription drugs must bear a label containing the statement "Federal law prohibits dispensing without prescription." This gives the retail druggist clear notice that he will be in violation of the Federal Food, Drug, and Cosmetic Act if he dispenses any drug so labeled without a prescription. This bill also specifies what information must be contained upon the label of the package dispensed to the patient. That label must contain the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.

This bill strengthens the controls over the habit-forming barbiturates. The problems of misuse of these drugs to the detriment of the public—especially of young people—are growing and must be controlled in the public interest. The bill requires that they be sold only on prescription and forbids unauthorized refills of prescriptions for them. In this, it is a definite and clear step forward. It is felt, however, that these drugs pose a special problem not common to all drugs because they are desired by addicts for nonmedical use. This will call for their special treatment, and the committee wishes it understood that in recommending the passage of this bill, as amended, it does so with the knowledge that further legislative consideration must be given to adequate barbiturate controls.

The bill does not relieve any person from any requirements of law, now existing or hereafter adopted, with respect to drugs covered by the narcotic control laws. Paragraph (5) of section 1 makes this clear.

Oral prescriptions

The present law does not recognize the practice of dispensing drugs on oral prescriptions. The committee feels that in this respect the law needs modification and clarification for the convenience of the public, the retail druggist, and the physician. The filling and refilling of prescriptions upon oral or telephone orders with proper safeguards should be permitted, and this bill gives statutory recognition to the practice of telephone dispensing.

It permits oral prescriptions for all drugs. However, in the case of habit-forming drugs, dangerous drugs, and new drugs limited to prescription sale, an oral prescription would have to be reduced promptly to writing and kept on file by the pharmacist. The oral order may be communicated to the dispenser by the prescriber himself or under his express authority.

Oral prescriptions for habit-forming drugs

The committee believes that the term "oral prescription," as used in the bill in connection with habit-forming drugs to which section 50 (d) of the act applies, should be given a construction which will assure that these drugs are used only upon the express order of a practitioner licensed by law to administer them. In fact,

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certain of these drugs, such as narcotics subject to the Harrison Narcotics Act may be dispensed only on a written prescription of a licensed practitioner, and this requirement is expressly preserved by the bill. (See par. (5) of the new sec. 503 (b).) The public interest clearly requires that other habit-forming drugs be dispensed and used only under the close and immediate supervision of a licensed practitioner. Accordingly, it is the intention of the committee that the term "oral prescription" as applied to these drugs, means an order communicated orally to the pharmacist by a practitioner licensed by law to administer such drugs, expressly prescribing such a drug, which is reduced promptly to writing and filed by the pharmacist. The Food and Drug Administration, within the limitations of its staffing, can check pharmacists' records to make sure that all habit-forming drugs sold are accounted for by prescriptions on file. The pharmacist, before he dispenses any such drug on oral order, must obtain satisfactory evidence, on the basis of consultation with the licensed practitioner or otherwise, that the order has been expressly authorized in each case by such practitioner.

The Federal Security Agency may adopt regulations needed for the efficient enforcement of this provision, and may find it desirable to require special records for any habit-forming drugs dispensed so that pharmacists and enforcement officials alike can readily detect any possible abuses of the oral prescription privilege extended for such drugs.

Refilling prescriptions

The bill, as amended, deals expressly with the troublesome problem of refilling prescriptions. Under the present law a drug dispensed by refilling a prescription without the knowledge or consent of the prescriber is misbranded and the dispenser is liable to criminal prosecution. The committee concluded that these provisions are too stringent and should be modified. There is no reason why the law should prohibit the refilling of prescriptions for drugs that are not dangerous and are suitable for use by a layman without medical supervision. The bill provides that prescriptions for such drugs may be freely refilled. But, here again, as to drugs which are habit-forming, or which are dangerous, or which are restricted by new drug applications to use under medical supervision, the bill requires that prescriptions may be refilled only with the prescriber's express authorization. This authorization may be either written or oral, but if it is given orally the dispenser must promptly reduce it to writing and keep it on file.

The provisions relating to the refilling of prescriptions are needed to meet a serious public health problem which has arisen from the indiscriminate refilling of prescriptions for dangerous and habit-forming drugs. A witness for the Food and Drug Administration cited cases in which death had occurred as a consequence of unauthorized prescription refills. The use of dangerous and habit-forming drugs must be under the supervision of the prescribing physician. This bill is intended to require that the licensed practitioner, if he has not authorized the refill in writing, be consulted by the pharmacist and the refill be authorized by such practitioner before any prescription for a drug that is limited to prescription sale may be refilled.

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EFFECT OF COMMITTEE AMENDMENTS

Amendment (1) was proposed by a firm engaged in selling through the mails to epileptic patients living throughout the United States a medication comprised principally of phenobarbital. Other provisions of the bill, to which the firm did not object, clarify and simplify the provisions of existing law regarding the labeling, sale, and dispensing of habit-forming and other dangerous drugs that should be sold only on prescription. These provisions are adequate to enable the Food and Drug Administration to compel such firms through appropriate court action, if necessary, to operate in a manner consistent with the public interest. The committee is aware of the obvious dangers to the public interest in the sale of barbiturates, including phenobarbital, without immediate and close medical supervision. The Food and Drug Administration has a responsibility in connection with the elimination of such dangers. This bill greatly strengthens the Administration's hand in discharging that responsibility.

The other two amendments were proposed by the combined drug trade in a statement signed by the National Association of Retail Druggists, the American Pharmaceutical Manufacturers' Association, the American Drug Manufacturers Association, and the Proprietary Association.

Amendment (2) was recommended because the associations felt the language it strikes out was of uncertain meaning and added nothing of importance to the bill. In any event, should a person place a statement on the label of a drug entirely safe for self-medication representing or implying that dispensing it without a prescription is prohibited by Federal law, that drug would be misbranded under the provision of law, section 502 (a), which forbids false or misleading labeling statements. Striking the language objected to does not relieve any manufacturer, regardless of the way in which he does business, from compliance with the requirement of section 502 (f) that all drugs not limited to prescription sale must bear adequate warnings and adequate directions for use telling the purchasing public what the drug is to be used for and how it is to be taken to accomplish the beneficial effects it is intended to have.

Amendment (3) was proposed to emphasize the fact that the responsibility for preparing adequate directions for use and appropriate warnings against misuse in the labeling of drugs that may be sold without a prescription is upon the manufacturer and not the retail druggist. It does nothing more than free the retail druggist of responsibility for supplementing the labeling of some manufacturers' drugs to give the public adequate directions for use and warnings against misuse. The druggist could rely in good faith upon the manufacturers' labeling for compliance with these requirements of the existing law. The amendment offers the druggist no protection against violations which arise if he sells a dangerous drug covered by paragraph (1) of the bill without meeting the prescription requirements.

Amendment (4) is a technical renumbering amendment.

EFFECTIVE DATE

Section 3 of the amended bill provides that its provisions shall take effect 6 months after the date of its enactment. This post- [p. 7] ponement of the effective date is considered necessary to permit manufacturers to meet the new labeling requirements.

SECTIONAL ANALYSIS

Section 1 of the bill amends the Federal Food, Drug, and Cosmetic Act by substituting for subsection (b) of section 503, relating to the labeling and dispensing of prescription drugs, a new subsection defining drugs that may be dispensed only on prescription and specifying the conditions under which such drugs may be dispensed.

Prescription drugs

Under paragraph (1) of the new subsection (b) prescription drugs are defined as drugs intended for use by man which fall within any one of three different categories. In limiting prescription drugs to those intended for use by man this new subsection differs from the present law, which refers to prescription drugs to include not only those dispensed on prescription of physicians and dentists, but also those dispensed on prescription of a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under section 502 (f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian. In the absence of any exempting regulations, these drugs will be subject to the labeling and dispensing requirements of the act applicable to over-the-counter drugs.

The three categories of prescription drugs defined as such in the bill are: (*a*) habit-forming drugs to which section 502 (d) of the act relating to drugs containing any narcotic or hypnotic substance, including barbituric acid, or habit-forming chemical derivatives thereof, is applicable; (*b*) drugs which, because of their toxicity or other potentiality for harmful effect, or the methods of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs; or (*c*) drugs which are limited by an effective application under section 505 of the act, relating to new drugs, to use under professional supervision.

Included in the first of these three categories are not only the habit-forming narcotics and chemical derivatives thereof, but also barbituric acid and its habit-forming derivatives, such as amytal, phenobarbital, pentobarbital, and the like. This category includes all of the drugs and derivatives thereof specified in section 502 (d) of the act and the regulations thereunder. Dispensing of these drugs must not only comply with the provisions of the bill, but also must conform to the requirements of that section, and the interstate label must bear the name and quantity or proportion of the habit-forming drug or derivatives and in juxtaposition therewith the statement: "Warning—May be habit forming."

The second category of prescription drugs, defined in subparagraph (B) of paragraph (1) of the new subsection (b) includes the so-called dangerous drugs. As noted elsewhere in this report, the phrase "not safe," as used in this subparagraph, is intended to have its ordinary meaning. Furthermore, in determining whether a drug is safe for use without medical supervision, there must be taken into consideration not only the drug's toxicity, but
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also other potentialities for harmful effect, the method by which it is used, and the collateral measures necessary to its safe use. The broad language of the definition contained in this subparagraph is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure their safe use. Such difficult borderline cases as may arise under this definition can be dealt with under the interpretative and rule-making power provided for in section 701 (a) of the act.

The third category of drugs defined as "prescription" drugs includes all new drugs restricted to prescription sale by effective new drug applications under section 505 of the act.

Written and oral prescriptions and refills

Paragraph (1) of the new subsection (b) also provides that a "prescription" drug (any drug falling in any one of the three categories referred to above) shall be dispensed only (1) upon a written prescription of a practitioner licensed by law to administer such drug, or (2) upon an oral prescription of such a practitioner, communicated by him or under his express authority to the pharmacist, if such prescription is promptly reduced to writing and filed by the pharmacist, or (3) by refilling any such written or oral prescription if such refilling is authorized by or under the express authority of the practitioner either in the original prescription or by oral order, which is reduced promptly to writing and filed by the pharmacist. The provisions with respect to oral prescriptions and refills do not apply, however, in the case of narcotics subject to the Internal Revenue Code (Harrison Narcotic Act), since subparagraph (5) of the new subsection (b) expressly safeguards the provisions of that act, and under those provisions and the regulations of the Bureau of Narcotics such drugs may be dispensed only on written prescription. Also, as pointed out elsewhere, with respect to other habit-forming drugs, oral prescriptions and refills are limited to situations in which the pharmacist obtains satisfactory evidence, on the basis of consultation with a licensed practitioner or otherwise, that the prescription or refill has been expressly authorized by such practitioner. A violation of the prescription requirements of paragraph (1) of the new subsection (b) is, under the provisions of this paragraph, deemed to be an act which results in the drug being misbranded while held for sale.

Labeling of prescription drugs

Paragraph (2) of the new subsection (b) provides that a drug dispensed on prescription shall be exempt from the provisions of the act relating to the misbranding of drugs except those which specify that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular (sec. 502 (a)), if it is an imitation of another drug or is offered for sale under the name of another drug (sec. 502 (i) (2) and (3)), if it is, or purports to be, or is represented as a drug composed wholly or partly of insulin or of penicillin or certain other antibiotics except under certain conditions (sec. 502 (k) and (l)). These provisions continue to apply to any drug subject to the act, whether sold over-the-counter or on prescription. Similarly, the packaging requirements set forth in section 502 (g) and (h) apply to all such drugs. Prescription drugs must, however, bear at the time of dispensing a label containing the name and address of the dispenser, the serial [p. 9] number and the date of the prescription or of its filling, the name of the practitioner, if stated in the prescription the name of the patient, and the directions for use and cautionary statements, if any, stated in the prescription. The exemption provided for by this paragraph does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of the subsection.

Exempt narcotics and similar drugs

Under paragraph (3) of the new subsection (b) the Administrator may by regulation remove habit-forming drugs, as defined in section 502 (d), and new drugs, from the prescription requirements contained in paragraph (1) of the subsection when these requirements are not necessary for the protection of the public health.

Prescription legend

Paragraph (4) of the new subsection requires that in addition to the labeling requirements in the case of prescription drugs specified in paragraph (2) of the subsection, the interstate label on such drugs must bear the statement "Caution: Federal law prohibits dispensing without prescription." On the other hand, over-the-counter drugs are forbidden to bear a label containing this caution statement. A prescription drug, the label on which does not bear the specified caution statement, is deemed to be misbranded. So too, is an over-the-counter drug, the label on which bears this or a substantially similar statement.

Narcotics and marihuana

Paragraph (5) of the new subsection provides that compliance with the requirements of the bill does not relieve any person from any other requirement prescribed by or under authority of law with respect to drugs now or hereafter within the classifications defined in the Harrison Narcotic Act (sec. 3220 of the Internal Revenue Code, 26 U.S.C. 3220), or marihuana, as defined in section 3238 (b) of the Internal Revenue Code (26 U.S.C. 3238 (b) of the Internal Revenue Code (26 U.S.C. 3238 (b)).

Good faith defense for retail druggists

Section 2 of the bill amends section 303 of the act, which specifies the penalties applicable to violations of the act. It adds to the several defenses available under subsection (c) of section 303 a new defense which has the effect of relieving from liability because of misbranding under section 502 (f) of the act any dispenser who makes delivery or proffers delivery of a drug in good faith if the labeling on such drug at the time of such delivery or proffered delivery contained the same directions for use and warning statements as were contained in the labeling at the time of receipt of the drug by such dispenser. This defense, however, is not applicable in the case of a drug which, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, and is not applicable to a prescription drug.

Effective date

Section 3 contains an effective date provision. In order to enable the drug industry to adapt its operations to the requirements specified in the bill, and to give the Food and Drug Administration

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time in which to develop procedures necessary to implement administration of the bill, it is provided that the provisions of the bill will not go into effect until 6 months have elapsed after the date of its enactment.

CHANGES IN EXISTING LAW

In compliance with subsection 4 of rule XXIX of the Standing Rules of the Senate, changes in the existing law made by the bill are shown as follows: (Existing law proposed to be omitted is enclosed in black brackets; new matter is printed in italics, existing law in which no change is proposed is shown in roman).

FEDERAL FOOD, DRUG AND COSMETIC ACT

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Administrator the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Administrator under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Administrator under this Act; *or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article.*

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Administrator is hereby directed to promulgate regulations exempting from any labeling or packing requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

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[(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).]

(b) (1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 502 (d) applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be

deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U. S. C. 3220), or to marihuana as defined in section 3238 (b) of the Internal Revenue Code (26 U. S. C. 3238 (b)). [p. 12]

1.13c (3) CONGRESSIONAL RECORD, VOL. 97 (1951)

1.13c (3) (a) Aug. 1: Amended and passed House, pp. 9333, 9334

[No Relevant Discussion on Pertinent Section]

1.13c (3) (b) Oct 15: Amended and passed Senate, pp. 13126, 13128, 13131

AMENDMENT OF SECTION 503 (B) FEDERAL FOOD, DRUG, AND COSMETIC ACT

Mr. McFARLAND. Mr. President, I move that the Senate proceed to the consideration of the bill (H. R. 3298) to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act.

The PRESIDING OFFICER. The question is on the motion of the Senator from Arizona.

The motion was agreed to; and the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare, with amendments.

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[p. 13126]

Mr. CASE. I believe the Senator has said that the bill comes before the Senate with the unanimous support of the Committee on Labor and Public Welfare.

Mr. HUMPHREY. That is correct.

The PRESIDING OFFICER. The clerk will state the committee amendments.

The amendments were, on page 3, line 4, after the word "by", to strike out "mail or otherwise without examination of the patient" and insert "mail"; in line 11, after the word "the", to strike out "production" and insert "protection"; in line 20, after the word "sentence", to strike out "or any other statement which represents or implies that the dispensing of the drug without the prescription of a licensed practitioner"; on page 4, after line 6, to insert:

> SEC. 2. Subsection (c) of section 303 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by striking out the period at the end of clause (3) and inserting in lieu thereof a semicolon and the following: "or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article."

And in line 19, to change the section number from "2" to "3."

The amendments were agreed to.

The PRESIDING OFFICER. The bill is open to further amendment.

Mr. HUMPHREY. Mr. President, I want to offer an amendment with regard to changing the title of the bill.

The PRESIDING OFFICER. That does not have to be done at this time.

The question is on the engrossment of the amendments and the third reading of the bill.

The amendments were ordered to be engrossed, and the bill to be read a third time.

The bill was read the third time, and passed.

[p. 13128]

Mr. HUMPHERY subsequently said: Mr. President, I move that the Senate insist upon its amendments, ask for a conference with the House thereon, and that the Chair appoint the conferees on the part of the Senate.

The motion was agreed to; and the Presiding Officer appointed Mr. LEHMAN, Mr. HUMPHREY, and Mr. IVES conferees on the part of the Senate.

[p. 13131]

1.13c (3) (c) Oct. 17: House concurs in Senate amendments, p. 13378

TO AMEND SECTION 503 (B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Mr. CROSSER. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H. R. 3298) an act to amend section 503 (b) of the Federal Food, Drug, and Cosmetic Act, with Senate amendments, and concur in the Senate amendments.

The Clerk read the title of the bill.

The Clerk read the Senate amendments, as follows:

Page 3, lines 4 and 5, strike out "mail or otherwise without examination of the patient" and insert "mail."

Page 3, line 19, strike out all after "sentence" down to and including "prohibited" in lines 21 and 22.

Page 4, after line 5, insert:

"SEC. 2. Subsection (c) of section 303 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by striking out the period at the end of clause (3) and inserting in lieu thereof a semicolon and the following: 'or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article'."

Page 4, line 6, strike out "2" and insert "3."

Amend the title so as to read: "An act to amend sections 303 (c) and 503 (b) of the Federal Food, Drug, and Cosmetic Act, as amended."

The SPEAKER. Is there objection to the request of the gentleman from Ohio [Mr. CROSSER]?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

[p. 13378]

1.13d 1953 REORGANIZATION PLAN I, §§5, 8, 67 STAT. 632

SEC. 5. *Transfers to the Department.*—All functions of the Federal Security Administrator are hereby transferred to the Secretary. All agencies of the Federal Security Agency, together with their respective functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available), and all other functions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available) of the Federal Security Agency are hereby transferred to the Department.

SEC. 6. *Performance of Functions of the Secretary.*—The Secretary may from time to time make such provisions as the Secretary deems appropriate authorizing the performance of any of the functions of the Secretary by any other officer, or by any agency or employee, of the Department.

SEC. 7. *Administrative Services.*—In the interest of economy and efficiency the Secretary may from time to time establish central administrative services in the fields of procurement, budgeting, accounting, personnel, library, legal, and other services and activities common to the several agencies of the Department; and the Secretary may effect such transfers within the Department of the personnel employed, the property and records used or held, and the funds available for use in connection with such administrative service activities as the Secretary may deem necessary for the conduct of any services so established: *Provided*, That no professional or substantive function vested by law in any officer shall be removed from the jurisdiction of such officer under this section.

[p. 632]

1.13e FOOD COLORING AMENDMENTS OF 1960

July 12, 1960, P.L. 86-618, Title I, §105(b), 74 Stat. 403

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), "404, 406 (b), 504, 506, 507, or 604", and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word
[p. 403]
"additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

[p. 404]

1.13e (1) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 795, 86th Cong., 1st Sess. (1959)

COLOR ADDITIVE AMENDMENTS OF 1959

AUGUST 21, 1959.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 2197]

The Committee on Labor and Public Welfare, to whom was referred the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

EXPLANATION

S. 2197 is designed to better protect the public health with respect to procedures necessary to assure the safety of color additives in foods, drugs, and cosmetics and to authorize the use of such color additives as have been predetermined to be perfectly safe in the amounts in which they are to be used. The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act with a scientifically sound and uniform system for the listing of color additives of any kind which may be safely used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Under existing law coal-tar colors may not be used in foods, drugs, or cosmetics unless they have been certified by the Food and Drug Administration as harmless and suitable for use. A recent Supreme Court decision has defined the "harmless" principle as meaning harmless regardless of the quantity of the coal-tar color which is being used. Thus, a color must be decertified if any quantity or concentration of the color is harmful, even though in lesser

[p. 1]

concentrations it may be perfectly safe. Because of this principle, as defined by the Supreme Court, it has been necessary for the Food and Drug Administration to withdraw certification of seven food colors. Seventeen additional colors have been proposed for delisting. The effect of the application of the "harmless" principle in terms of existing law is to cause many of the coal-tar colors widely used in industry to be no longer available, and the number of colors withdrawn will eventually seriously handicap manufacturers of foods, drugs, and cosmetics in the production of products in the manner that is customary and usual.

Many food industries find themselves seriously affected by the delisting of colors. If additional proposed delistings are accomplished, similar effect is faced by drug and cosmetic industries. The very existence of many products depends upon the use of suitable color.

This legislation is necessary, because it will give the Secretary of Health, Education, and Welfare a flexibility, which he does not have under the present law, to certify coal-tar colors within tolerance limits which he determines are safe.

Two amendments to the bill as originally introduced were adopted by the committee. Both amendments were developed cooperatively by the committee staff, representatives of the industries concerned, and representatives of the Food and Drug Administration. Both have been declared acceptable by the Administration and by industry. Their objectives are, first, to permit those additives found "safe" by the Secretary under the procedures set forth in the Food Additives Amendments Act of 1958 to be considered "safe" when used as color additives, and, secondly, to relieve the Administration from the obligation of requiring the use of certain analytical methods, when, in its opinion, they are not needed.

The bill as amended has the endorsement of the Administration and of the following business groups which have concerned themselves with the legislation: The Certified Color Industry Committee, the Toilet Goods Association, the National Association of Margarine Manufacturers, the International Association of Ice Cream Manufacturers, the Grocery Manufacturers of America, and the National Confectioners Association.

S. 2197 was introduced at the request of the Department of Health, Education, and Welfare with the approval of the Bureau of the Budget.

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[Arthur S. Flemming, Secretary, Department of Health, Education, and Welfare]

"3. There is a need for making applicable to all color uses and all types of color — whether they be coal-tar colors or others — the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors; there is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives." [p. 4]

The technical provisions and approach of this bill are summarized in detail in the section-by-section analysis which follows.

SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1959"

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes)) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are, when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85–929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the abovementioned changes; and contains transitional provisions for commercially established colors.

[p. 12]

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to, sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

[p. 17]

1.13e (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1761, 86th Cong., 2d Sess. (1960)

COLOR ADDITIVE AMENDMENTS OF 1960

JUNE 7, 1960.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7624]

The Committee on Interstate Foreign Commerce, to whom was referred the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

[p. 1]

PURPOSE OF LEGISLATION

The purpose of this bill is to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerances, under which such additives may be safely used.

GENERAL SUMMARY

The committee bill—

(1) takes "color additives" out of the scope of the Food Additives Amendment of 1958;

(2) repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406 (b), 504, and 604);

(3) enacts new, integrated provisions for the separate listing of suitable "color additives," safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted;

(4) provides for the certification (or exemption from certification) of listed color additives for such permitted uses;

(5) adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and

(6) contains transitional provisions for commercially established colors.

HEARINGS

Extensive hearings were held by the committee on this legislation in January, February, March, and May 1960 and a large number of witnesses were heard. The committee also heard from a distinguished group of scientific experts, selected by the President of the National Academy of Sciences, which discussed the scientific problems involved in this legislation, with special emphasis on the Delaney anticancer clause.

[p. 6]

5. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to

grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. The committee agrees with the Secretary of Health, Education, and Welfare, however, that authority to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

[p. 15]

(2) Color additives exempted under Food Additives Amendment (p. 9, beginning on line 8 of reported bill)

This committee amendment revises proposed section 706(b) (4) by transferring the provisions of subparagraphs (B) and (C) thereof, in consolidated and modified form, to proposed section 706 (b) (5) (see discussion immediately below) and adding a proviso to the revised section 706(b) (4) providing that a color additive shall be deemed to be suitable and safe for listing for use generally in or on food while there is in effect a published finding by the Secretary declaring that such additive is exempt under the Food Additives Amendment of 1958 because of its being generally recognized by qualified experts as safe for its intended use as provided in section 201(s) of the act.

(3) Analytical methods for color additives (p. 11, beginning on line 1 of reported bill)

This committee amendment adds a new subparagraph (iv) to proposed section 706 (b) (5) (A) in the bill, which consolidates and modifies the provisions of subparagraphs (B) and (C) of proposed section 706(b) (4) in the bill as introduced. These subsections deal

[p. 18]

with practicable methods of analysis for color additives and for determining the identity and quantity of such additives or their reaction products in foods, drugs, and cosmetics.

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analysis are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe. The committee amendment meets this objection without impairing consumer health protection.

[p. 19]

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

[p. 29]

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a [coal-tar] color *additive* not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the [coal-tar] color *additive,* to the effect that such color *additive* was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article.

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[p. 36]

EXPLANATION OF PRINCIPAL FEATURES AND PURPOSES OF PROPOSED COLOR ADDITIVE AMENDMENTS OF 1959

The letter of transmittal briefly summarizes the general objectives of this legislative proposal, the principal reasons which gave rise to it, and previous amendments to the Federal Food, Drug, and Cosmetic Act which, in the case of Food, show congressional endorsement of its key principle, that is, recognition of the scientific soundness of considering the level and other conditions of use in determining the safety of a color additive. A fuller explanation is, however, necessary to an adequate understanding of the major provisions of the bill and their purposes against the background of existing law. In addition, a section-by-section analysis is enclosed for the benefit of those who desire to become conversant with the details of each provision.

A. PRESENT LAW

Under present law, the treatment of color additives differs radically as between the so-called coal-tar colors and others. (For explanation of the technical difference between so-called coal-tar colors and others, see the discussion under "Major Changes Proposed.")

1. *Coal-tar colors.*—The act requires the Secretary to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, or cosmetics; and a food, drug, or cosmetic (other than a hair dye) is deemed adulterated if it bears or contains a coal-tar color other than from a certified batch (except that in the case of drugs this provision applies only where the coal-tar color is used for coloring
[p. 63]
purposes only). (See secs. 402(c), 406(b), 501(a)(4), 504, 601(e), 604, and 701(e) and (f) of the act.) Under these provisions, we are without power to admit a color to listing under tolerance limitations. (*Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153 (1958)).

2. *Other colors.*—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirement in the case of cosmetics or drugs (except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act).

On the other hand, with respect to their use in food, non-coal-tar coloring materials which are classed as "food additives" under the recent Food Additives Amendment of 1958 (Public Law 85-929) are subject to a requirement of official safety clearance, and to the establishment of tolerance limitations and other conditions of safe use where necessary for public health protection, except that colors which were in commercial use before January 1, 1958, are allowed a grace period for compliance; this period will expire not later than March 6, 1961. Such "food additive" colors, however, are not subject to any requirement of "batch" certification even if, in our view, this would be desirable for the protection of food processors and housewives using the color.

B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility.*—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics, other than hair dyes. This would be accomplished by excepting color additives, as defined in the bill, from the

term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived. The present bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would, therefore, establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement

[p. 64]

was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, Delaney committee—see House Report No. 2356, and House Report No. 2182, 82d Congress—and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

2. *Safety-of-use principle.*—The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use, including maximum tolerance limitations, as are determined to be necessary to assure the safety of such use.

3. *Comprehensive lists.*—The bill, however, retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as

safe for use. While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies — in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices— we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color.

4. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. We believe, however, that power to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

5. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act, that is, title I of the bill, would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The "commercially established" color additives falling under these transitional provisions are *(a)* those coal-tar colors of which a batch or batches were actually cer-

[p. 65]

tified prior to the date of enactment of the bill, and *(b)* those non-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic, except that in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

C. NEED FOR THE BILL

The interests of consumer protection and of the food, drug, cosmetic; and color industries combine to make urgent the need for enactment of this bill.

1. Consumer protection

First. — Under present law the Government has to perform extensive research to determine whether the colors now listed and being used are in fact harmless and suitable for use in food, drugs, and cosmetics. This testing may require up to 20 years. The bill would require industry to assume the burden of this testing, and would require the tests to be completed within 2½ years or, in individual cases, such additional testing period as is shown to be required and to be consistent with public-health protection. Further, it would allow the Department to place safe tolerance limitations on the amount of color that may be used and the products on which it may be used during this transition period; the Department has no such authority under present law.

[p. 66]

1.13e (3) CONGRESSIONAL RECORD

1.13e (3) (a) VOL. 105 (1959), Aug. 24: Amended and passed Senate, p. 16778

[No Relevant Discussion on Pertinent Section]

1.13e (3) (b) VOL. 106 (1960), June 25: Amended and passed House, pp. 14373, 14377

[No Relevant Discussion on Pertinent Section]

1.13e (3) (c) VOL. 106 (1960), June 30: Senate concurs in House amendments, p. 15135

[No Relevant Discussion on Pertinent Section]

1.13f DRUG ABUSE CONTROL AMENDMENTS OF 1965

July 15, 1965, P.L. 89–74, §§7, 9(d), 79 Stat. 233, 235

PENALTIES

SEC. 7 (a) Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)) is amended by inserting after the final word "fine" and before the period the following: ":*Provided, however,* That any person who, having attained his eighteenth birthday, violates section 301(q) (2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his twenty-first birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than $5,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than $15,000, or both such imprisonment and fine".

(b) Section 303 (b) of such Act (21 U.S.C. 333 (b)) is amended by inserting after the word "shall" the following: "(except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses)".

[p. 233]

SEC. 9.

* * * * * * *

(d) Section 303 of such Act (21 U.S.C. 333(c)) is amended by inserting immediately before the period at the end thereof the following: "; or (5) for having violated section 301(i) (2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i) (3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug".

[p. 235]

1.13f (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 130, 89th Cong., 1st Sess. (1965)

DRUG ABUSE CONTROL AMENDMENTS OF 1965

MARCH 2, 1965.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 2]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 2) to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are a substitute for the text of the bill which is printed in italic type in the bill, as reported, and an amendment to the title which conforms it to the substitute amendment.

PURPOSE OF THE BILL

The bill provides increased controls over the distribution of barbiturates, amphetamines, and other drugs having a similar effect on the central nervous system. The controls are accomplished through increased recordkeeping and inspection requirements, through providing for control over intrastate traffic in these drugs because of its effect on interstate traffic, and through making possession of these drugs (other than by the user) illegal outside of the legitimate channels of commerce. The bill also increases the authority of the Department of Health, Education, and Welfare over counterfeit drugs.

[p. 1]

SECTION 7. PENALTIES

This section amends section 303 of the Federal Food, Drug, and Cosmetic Act so as to provide a special penalty in any case where a person who is 18 years of age or older is convicted of selling, delivering, or otherwise disposing of any depressant or stimulant drug to any person who is younger than 18 years of age. In the case of a first offense the penalty would be imprisonment for not more than 2 years, or a fine of not more than $5,000, or both, and, in the case of a second or subsequent offense, imprisonment for not more than 6 years, or a fine of not more than $15,000, or both.

[p. 19]

SECTION 9. COUNTERFEITING OF DRUGS

(1) there is a substantial traffic in counterfeit drugs;

(2) such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiters;

(3) the controls for the suppression of the traffic in counterfeit drugs are inadequate; and

(4) these factors require enactment of additional controls with respect to counterfeit drugs without regard to their interstate or intrastate origins.

Subsection (b) adds to section 201 of the Federal Food, Drug, and Cosmetic Act a definition of "counterfeit drug." As defined, the term means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Subsection (c) amends section 301 of the Federal Food, Drug, and Cosmetic Act so as to add to the list of things prohibited by that section the (1) making, selling, disposing of, or keeping in possession, control, or custody, or concealing anything designed to reproduce the identifying mark of another or any likeness thereof upon any drug or container or labeling thereof so as to render such drug a counterfeit drug, or (2) the doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

Subsection (d) amends section 303 of the Federal Food, Drug, and Cosmetic Act so as to provide that no person shall be subject to a penalty for having done any act described in clause (1) of the preceding paragraph if he acted in good faith and had no reason to believe that use of any such thing would result in a drug being a counterfeit drug, or for having done any act described in clause (2) of the preceding paragraph if he acted in good faith and had no reason to believe that the drug was a counterfeit drug. [p. 20]

1.13f (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 337, 89th Cong., 1st Sess. (1965)

DRUG ABUSE CONTROL AMENDMENTS OF 1965

JUNE 21, 1965.—Ordered to be printed

Mr. YARBOROUGH, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 2]

The Committee on Labor and Public Welfare, to whom was referred the bill (H.R. 2) to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

PURPOSE

The bill provides increased controls over the distribution of barbiturates, amphetamines, and other drugs having a similar effect on the central nervous system. The controls are accomplished through increased recordkeeping and inspection requirements, through providing for control over intrastate traffic in these drugs because of its effect on interstate traffic, and through making possession of these drugs (other than by the user) illegal outside of the legitimate channels of commerce. The bill also increases the authority of the Department of Health, Education, and Welfare over counterfeit drugs.

A bill with the same objectives in the control of stimulant and depressant drugs was sponsored by Senator Dodd and unanimously approved by the Senate last year. That bill was S. 2628.

[p. 1]

Section 7 provides for increased maximum penalties for persons over 18 who illegally dispense a depressant or stimulant drug to persons under 21, i.e., up to 2 years or $5,000 or both for the first offense, and 6 years or $15,000 or both for a subsequent offense, as compared to the maximum of 1 year and $1,000 for a first offense (not shown to involve an intent to defraud or mislead) and 3 years and $10,000 for a subsequent offense (or for first offenses committed with intent to defraud or mislead) otherwise applicable under the Food, Drug, and Cosmetic Act.

* * * * * * *

Section 9 (a) contains a finding that there is a substantial traffic in counterfeit drugs, that such traffic poses a serious health hazard, that, while such drugs are misbranded under section 502 (i) of the Food, Drug, and Cosmetic Act, controls for suppression of the traffic are inadequate because of the difficulty of determining the place of origin and the fact that implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls as to such drugs without regard to their interstate or intrastate origin.

Section 9 (b) defines the term "counterfeit drug" to mean "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than the person or persons who, in fact, manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

Section 9 (c) prohibits the making, selling, disposing of, possessing, or concealing of equipment for counterfeiting drugs. It also prohibits the doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. Persons acting in good faith and having no reason to believe that their acts, or the use of the equipment, would result in a counterfeit drug, or that the drugs in their possession are counterfeits, are exempted from the criminal penalties of the statute because of acts prohibited by section 9 (c).

[p. 12]

1.13f (3) CONGRESSIONAL RECORD, VOL. 111 (1965)

1.13f (3) (a) March 10: Amended and passed House, pp. 4702–4703

[No Relevant Discussion on Pertinent Section]

1.13f (3) (b) June 23: Amended and passed Senate, p. 14609

[No Relevant Discussion on Pertinent Section]

1.13f (3) (c) July 8: House concurs in Senate amendments, pp. 15977–15978

[No Relevant Discussion on Pertinent Section]

1.13g FEDERAL FOOD, DRUG, AND COSMETIC ACT LSD AMENDMENTS

October 24, 1968, P.L. 90–639, §3, 82 Stat. 1361

SEC. 3. Section 303 of such Act (21 U.S.C. 333) is amended by striking out subsections (a) and (b) and inserting in lieu thereof the following new subsections:

"SEC. 303. (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

"(b) (1) Any person who violates clause (1), (2), or (3) (A) of section 301 (q), or violates, with respect to a depressant or stimulant drug, any of the provisions of paragraph (3) of section 301 (i), shall, except as otherwise provided in paragraph (2) of this subsection, be imprisoned for not more than five years or fined not more than $10,000, or both.

[p. 1361]

"(2) Any person eighteen or older who violates clause (2) of section 301 (q) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who is under twenty-one, shall be imprisoned for not more than ten years or fined not more than $15,000, or both, except that if any person commits such a violation after a conviction of him under this paragraph has become final, he shall be imprisoned for not more than fifteen years or fined not more than $20,000, or both.

"(3) (A) Except as otherwise provided in this subparagraph or in subparagraph (B), any person who violates clause (3) (B) of section 301 (q) shall be imprisoned for not more than one year or fined not more than $1,000, or both. If any person commits such a violation after two prior convictions of him for violation of such clause have become final, he shall be imprisoned for not more than three years or fined not more than $10,000, or both.

"(B) In the case of any person who is convicted for the first time of violating a provision of section 301 (q) and whose conviction was for violating clause (3) (B) of such section, the court may suspend the imposition or execution of sentence and place such person on probation subject to such conditions as the court may impose and for such period, not to exceed one year, as the court may prescribe. The court may, in its discretion, unconditionally discharge such person from probation prior to the expiration of the maximum period prescribed for such person's probation. Such discharge shall automatically set aside the conviction, and the court shall issue to such person a certificate to that effect. If during the period of his probation such person does not violate any of the conditions of his probation, his conviction shall at the expiration of such period be automatically set aside, and the court shall issue to such person a certificate to that effect."

[p. 1362]

1.13g (1) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 1546, 90th Cong., 2d Sess. (1968)

INCREASING PENALTIES FOR UNLAWFUL ACTS INVOLVING LSD AND OTHER DEPRESSANT AND STIMULANT DRUGS

JUNE 12, 1968.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 14096]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to prescribe penalties for the possession of LSD and other hallucinogenic drugs by unauthorized persons, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

That section 201 (v) (3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by striking out "any drug" and inserting in lieu thereof "lysergic acid diethylamide and any other drug".

SEC. 2. (a) Section 511 (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a (c)) is amended to read as follows:

"(c) No person, other than a person described in subsection (a) or (b) (2) of this section, shall—

"(1) possess any depressant or stimulant drug for sale, delivery, or other disposal to another, or

"(2) otherwise possess any such drug unless such drug was obtained directly, or pursuant to a valid prescription, from a practitioner (licensed by law to prescribe or administer such a drug) while acting in the course of his professional practice."

(b) Clause (3) of paragraph (q) of section 301 of such Act (21 U.S.C. 331 (q) (3) is amended to read as follows: "(3) (A) the possession of a drug in violation of section 511 (c) (1), or (B) the possession of a drug in violation of section 511 (c) (2);".

SEC. 3. Section 303 of such Act (21 U.S.C. 333) is amended by striking out subsections (a) and (b) inserting in lieu thereof the following new subsections:

[p. 1]

"SEC. 303. (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

"(b) (1) Any person who violates clause (1), (2), or (3) (A) of section 301 (q), or violates, with respect to a depressant or stimulant drug, any of the provisions of paragraph (3) of section 301 (i), shall, except as otherwise provided in paragraph (2) of this subsection, be imprisoned for not more than five years or fined not more than $10,000, or both.

"(2) Any person eighteen or older who violates clause (2) of section 301 (q) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who is under twenty-one, shall be imprisoned for not more than ten years or fined not more than $15,000, or both, except that if any person commits such a violation after a conviction of him under this paragraph has become final, he shall be imprisoned for not more than fifteen years or fined not more than $20,000, or both.

"(3) (A) Except as provided in subparagraph (B) of this paragraph, any person who violates clause (3) (B) of section 301 (q) shall (1) be imprisoned for not more than one year or fined not more than $1,000, or both, if he has not been convicted of violating any provision of section 301 (q) prior to his conviction for violating such clause, or (2) be imprisoned for not more than

three years or fined not more than $10,000, or both, if he has been convicted of violating a provision of such section prior to his conviction for violating such clause.

"(B) In the case of any person who is convicted for the first time of violating a provision of section 301 (q) and whose conviction was for violating clause (3) (B) of such section, the court may suspend the imposition or execution of sentence and place such person on probation subject to such conditions as the court may impose and for such period, not to exceed one year, as the court may prescribe. The court may, in its discretion, unconditionally discharge such person from probation prior to the expiration of the maximum period prescribed for such person's probation. Such discharge shall automatically set aside the conviction, and the court shall issue to such person a certificate to that effect. If during the period of his probation such person does not violate any of the conditions of his probation, his conviction shall at the expiration of such period be automatically set aside, and the court shall issue to such person a certificate to that effect."

SEC. 4. It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, his highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse.

SEC. 5. The amendments made by this Act shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act committed after the date of the enactment of this Act.

Amend the title so as to read:

A bill to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes.

PRINCIPAL PURPOSE OF THE BILL

As reported by the committee, the bill would provide increased penalties for persons trafficking illegally in barbiturates, depressants, amphetamines, and LSD, and other halucinogens, and would make possession of barbiturates, depressants, amphetamines and hallucinogenic drugs a misdemeanor, unless the drugs in question were obtained pursuant to a valid prescription. Provision is made for special treatment of first offenders accused of illegal possession of the drugs in question.

[p. 2]

Since the provisions of the bill with respect to penalties for possession are intended primarily as an aid to law enforcement agencies, and the other provisions provide increased penalties for acts already made illegal, it is not anticipated that any increased appropriations would be required to carry out the act.

[p. 3]

PENALTIES FOR POSSESSION

In the 1965 Drug Abuse Control Amendments, possession of dangerous drugs for personal use was not made a prohibited act, although possession for purposes of sale or other disposition to another outside of legitimate channels of trade was made a prohibited act, subject to fine and imprisonment.

Testimony presented at the hearings indicated that a number of physicians feel that possession for personal use should be controlled through educational programs, and not through making such possession a criminal offense. This feeling appears to be based generally upon the theory that the adverse effects, particularly on the young, of arrest and prosecution, with the possibility of consequent criminal records, overweigh the adverse effects of drug abuse.

This approach, of course, involves subjective judgments, balancing adverse physical and psychological effects of drug abuse against the psychological effects of fear of arrest, and possible arrest and prosecution. The view that possession should not be a prohibited act is not however a view unanimously held by the medical profession. The committee received testimony from physicians in support of the approach of the bill. [p. 6]

In general, law enforcement officers favor making possession of drugs illegally obtained a prohibited act. Not only does the presence of such a penalty in the law operate as a deterrent, penalties for possession serve greatly to aid in law enforcement. It is frequently difficult to obtain evidence sufficient to sustain a successful prosecution against a person trafficking in drugs; however, where the possession of such drugs is illegal, arrests and prosecution for possession can serve to take these traffickers out of circulation and thereby curtail illicit traffic in these drugs.

A further reason for making the possession of dangerous drugs obtained illictly a prohibited act is to counter the feeling among some young people that abuse of dangerous drugs is not detrimental to them, since there is no penalty for personal abuse.

APPROACH OF THE BILL

The committee has attempted to strike a balance between the conflicting points of view on the question of whether or not possession of dangerous drugs obtained illicitly should be made a prohibited act, subject to fine or imprisonment. The bill makes possession of dangerous drugs a misdemeanor subject to imprisonment up to 1 year and a fine up to $1,000 for a first offender, with a penalty of up to 3 years' imprisonment and up to $10,000 fine for the second and subsequent offenses. The bill also provides, however, that where an individual is charged with simple possession of dangerous drugs obtained without a doctor's prescription, and he has not previously been convicted of a violation of the law with respect to dangerous drugs, the court may, in lieu of fine or imprisonment, place the offender upon probation for such period, up to 1 year, as the court might determine, subject to such conditions as the court may impose. For example, a person charged with the first offense of possession could be required to obtain psychiatric help as a condition of probation. The court is authorized to discharge the offender from probation prior to the expiration of 1 year. If the offender is discharged from probation by the court, or if, at the completion of the period of probation prescribed by the court, the court determines that the offender has fully complied with the terms and conditions of probation, the conviction is automatically set aside and the court is required to issue a certificate to the offender to this effect.

In this fashion, persons convicted of a first offense for personal use may, in the discretion of the court, be treated with leniency, and upon compliance with the conditions of probation, wind up with no criminal record. In the event of a second offense against the laws controlling dangerous drugs by a person whose conviction has been set aside under the previous procedure, that individual will be treated as a first offender (*see Stevenson*, v. *U.S.* 380 F2d 590, 593 (D.C. Cir. 1967); however, in the case of the second offense the court will have available to it as a part of normal presentence investigations, knowledge of the previous set-aside conviction, and the court will take this fact into account in determining whether or not to grant probation to the offender.

Of course, if the offender is a juvenile (below the age of 18), the Juvenile Offenders Act will apply to him, which means that [p. 7] he will be treated in the same fashion as other juvenile offenders against Federal law are treated; and as an adult will have no criminal record. In addition, in the case of a youthful offender (below the age of 26), the Federal Youth Offenders Act will also be applicable, which also provides for probation, and under some circumstances, the setting aside of a conviction.

In addition to the above protections for youthful offenders, the Department of Justice has established administratively a system referred to as the Brooklyn Plan, under which the U.S. attorney, may, either prior to or after arrest, call the juvenile offenders and parents or guardian where appropriate to his office, and withhold arrest or prosecution of the offender in appropriate cases where, in the discretion of the U.S. attorney, it appears that the purposes of the law can be better served thereby.

The committee has therefore struck a balance in the reported bill between the separate points of view concerning penalties for possession of dangerous drugs. The committee has prescribed penalties for possession, both as an aid to law enforcement and for its deterrent effect; however, the committee has added to the protection of the Brooklyn Plan, the Juvenile Offenders Act, and the Federal Youth Corrections Act further protections designed to minimize the long term adverse consequences upon a youth of a conviction of a violation of the prohibition against possession of dangerous drugs.

In his message on the Challenge of Crime to Our Society of February 7, 1968 (H. Doc. 250, 90th Cong.) the President requested that the Congress enact legislation to make the illegal manufacture, sale, or distribution of LSD and other dangerous drugs a felony and the illegal possession of these drugs a misdemeanor. This bill carries out that recommendation.

Until April of this year, enforcement of this act was the responsibility of the Food and Drug Administration, acting through the Bureau of Drug Abuse Control. Reorganization Plan No. 1 of 1968 establishing the Bureau of Narcotics and Dangerous Drugs, transferred to the Attorney General all functions of the Secretary of Health, Education, and Welfare under this act except the function of regulating the counterfeiting of drugs which are not controlled depressant or stimulant drugs.

INCREASED PENALTIES FOR TRAFFICKING IN DANGEROUS DRUGS

Under existing law (sec. 301 of the Federal Food, Drug, and Cosmetic Act), the following are prohibited acts:

(1) Manufacture, compounding, or processing of a controlled barbiturate, depressant, amphetamine, or hallucinogen outside legitimate channels of trade;

(2) Sale, delivery, or other disposition of such a drug outside legitimate channels of trade; and

(3) Possession of such dangerous drug except where obtained through legitimate channels, and except for personal use by the possessor or a member of his household or for administration to an animal owned by him or a member of his household.

Violation of any of the above provisions is subject to the same penalties as are prescribed for other violations of the Food and

Drug Act; namely up to 1 year imprisonment or $1,000 fine, or both, for a first offense and up to 3 years imprisonment or up to [p. 8] $10,000 fine, or both, for a second or subsequent offense, or for a first offense committed with intent to defraud or mislead. Higher penalties are prescribed for illegal sales of controlled drugs to minors.

The reported bill follows the recommendations of the administration, and makes all offenses involving illegal trafficking in controlled barbiturates, amphetamines, or hallucinogens a felony, subject to imprisonment of up to 5 years, or a fine of up to $10,000, or both. In case of a sale to a minor by a person over the age of 18, the penalties prescribed in the bill are up to 10 years imprisonment for a first offense or a fine of not more than $15,000, or both, and in case of a second or subsequent offense, imprisonment for more than 15 years or a fine of not more than $20,000, or both.

SECTION-BY-SECTION SUMMARY OF THE COMMITTEE AMENDMENT

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[p. 9]

Revision of penalties for offenses involving depressant or stimulant drugs

Section 3 of the committee amendment makes a general revision in the penalties prescribed in section 303 of the act for offenses involving depressant or stimulant drugs. Examples of such offenses are the unlawful manufacturing, sale, and possession of those drugs, and failure to comply with recordkeeping, plant inspection, and prescription requirements.

The penalties under existing law are as follows:

(1) A first offense involving a depressant or stimulant drug committed without the intent to defraud or mislead is a misdemeanor punishable by a fine not exceeding $1,000 or imprisonment for not more than a year, or both.

(2) A second or subsequent offense or one committed with the intent to defraud or mislead is a felony punishable by a fine not exceeding $10,000 or imprisonment for not more than 3 years, or both.

(3) There is an exception to the provisions described in the preceding paragraphs. If a person 18 or over sells or otherwise unlawfully disposes of a depressant or stimulant drug to a person under 21, the penalty for the first offense is a fine not exceeding $5,000 or imprisonment for not more than 2 years, or both, but if the offense is committed with the intent to defraud or mislead,

the penalty would be the one described in paragraph (2). The penalty for second or subsequent offenses is a fine not exceeding $15,000 or imprisonment for not more than 6 years, or both.

The committee amendment makes the following changes:

(1) In general, if the offense involves the unlawful manufacturing of, sale or other disposal of, or possession with intent to sell, a depressant or stimulant drug or involves counterfeit depressant or stimulant drugs, the penalty (prescribed in the new sec. 303 (b) (1) of the act) is a fine not exceeding $10,000 or imprisonment for not more than 5 years, or both.

(2) A stiffer penalty is provided in the new section 303 (b) (2) of the act for unlawful sales or other disposals of depressant or stimulant drugs by persons over 18 to persons under 21. The penalty for the first offense is a fine not exceeding $15,000 or imprisonment for not more than 10 years, or both. The penalty provision for second or subsequent offenses increases the maximum fine to $20,000 and the maximum imprisonment to 15 years.

(3) The penalty provision in the new section 303 (b) (3) for possession of a depressant or stimulant drug for purposes other than sale or other disposal contains a special provision for a person whose conviction for such possession is his first conviction for any offense under the act. The court may suspend the imposition or execution of sentence on that person and place him on probation for not to exceed 1 year. If the court unconditionally discharges that person from probation prior to the prescribed probation period or if he completes his probation period without violating any of the conditions of his probation, the conviction of that person is automatically set aside. This provision is similar to provisions in the Federal Youth Corrections Act (18 U.S.C. 5005-5026). [p. 10]

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

* * * * * * *

[p. 12]

PENALTIES

[SEC. 303 (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine: *Provided, however,* That any person who, having attained his eighteenth birthday, violates section 301(q) (2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his twenty-first birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than $5,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than $15,000, or both such imprisonment and fine.

[(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall (except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses) be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.]

[p. 14]

Sec. 303. (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(b)(1) Any person who violates clause (1), (2), or (3)(A) of section 301(q), or violates, with respect to a depressant or stimulant drug, any of the provisions of paragraph (3) of section 301(i), shall, except as otherwise provided in paragraph (2) of this subsection, be imprisoned for not more than five years or fined not more than $10,000, or both.

(2) Any person eighteen or older who violates clause (2) of section 301 (q) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who is under twenty-one, shall be imprisoned for not more than ten years or fined

not more than $15,000, or both, except that if any person commits such a violation after a conviction of him under this paragraph has become final, he shall be imprisoned for not more than fifteen years or fined not more than $20,000, or both.

(3) (A) Except as provided in subparagraph (B) of this paragraph, any person who violates clause (3) (B) of section 301 (q) shall (1) be imprisoned for not more than one year or fined not more than $1,000, or both, if he has not been convicted of violating any provision of section 301 (q) prior to his conviction for violating such clause, or (2) be imprisoned for not more than three years or fined not more than $10,000, or both, if he has been convicted of violating a provision of such section prior to his conviction for violating such clause.

(B) In the case of any person who is convicted for the first time of violating a provision of section 301 (q) and whose conviction was for violating clause (3) (B) of such section, the court may suspend the imposition or execution of sentence and place such person on probation subject to such conditions as the court may impose and for such period, not to exceed one year, as the court may prescribe. The court may, in its discretion, unconditionally discharge such person from probation prior to the expiration of the maximum period prescribed for such person's probation. Such discharge shall automatically set aside the conviction, and the court shall issue to such person a certificate to that effect. If during the period of his probation such person does not violate any of the conditions of his probation, his conviction shall at the expiration of such period be automatically set aside, and the court shall issue to such person a certificate to that effect.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case

[p. 15]

of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d) that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503 (b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of article; or (5) for having violated section 301 (i) (2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301 (i) (3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

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1.13g (2) SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

S. REP. No. 1609, 90th Cong., 2d Sess. (1968)

AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

OCTOBER 2 (legislative day, SEPTEMBER 24), 1968,—Ordered to be printed

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Mr. HILL, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany H.R. 14096]

The Committee on Labor and Public Welfare, to which was referred the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

PRINCIPAL PURPOSE OF THE BILL

As reported by the committee, the bill would provide increased penalties for persons trafficking illegally in barbiturates, depressants, amphetamines, and LSD and other hallucinogens, and would make possession of barbiturates, depressants, amphetamines and hallucinogenic drugs illegal, unless the drugs in question were obtained pursuant to a valid prescription. Provision is made for special treatment of first offenders accused of illegal possession of the drugs in question.

Since the provisions of the bill with respect to penalties for possession are intended primarily as an aid to law enforcement agencies, and the other provisions provide increased penalties for acts already made illegal, it is not anticipated that any increased appropriations would be required to carry out this act.

[p. 1]

PENALTIES FOR POSSESSION

In the 1965 Drug Abuse Control Amendments, possession of dangerous drugs for personal use was not made a prohibited act, although possession for purposes of sale or other disposition to another outside of legitimate channels of trade was made a prohibited act, subject to fine and imprisonment.

A number of physicians feel that possession for personal use should be controlled through educational programs, and not through making such possession a criminal offense. This feeling appears to be based generally upon the theory that the adverse effects, particularly on the young, of arrest and prosecution, with the possibility of consequent criminal records, overweigh the adverse effects of drug abuse.

This approach of course, involves subjective judgments, balancing adverse physical and psychological effects of drug abuse against the psychological effects of fear of arrest, and possible arrest and prosecution. The view that possession should not be a prohibited act is not however a view unanimously held by the medical profession.

In general, law enforcement officers favor making possession of drugs illegally obtained a prohibited act. Not only does the presence of such a penalty in the law operate as a deterrent, penalties for possession serve greatly to aid in law enforcement. It is frequently difficult to obtain evidence sufficient to sustain a successful prosecution against a person trafficking in drugs; however, where the possession of such drugs is illegal, arrests and prosecution for possession can serve to take these traffickers out of circulation and thereby curtail illicit traffic in these drugs.

A further reason for making the possession of dangerous drugs obtained illicitly a prohibited act is to counter the feeling among

[p. 4]

some young people that abuse of dangerous drugs is not detrimental to them, since there is no penalty for personal abuse.

[p. 5]

INCREASED PENALTIES FOR TRAFFICKING IN DANGEROUS DRUGS

Under existing law (sec. 301 of the Federal Food, Drug, and Cosmetic Act), the following are prohibited acts:

> (1) Manufacture, compounding, or processing of a controlled barbiturate, depressant, amphetamine, or hallucinogen outside legitimate channels of trade;
>
> (2) Sale, delivery, or other disposition of such a drug outside legitimate channels of trade; and
>
> (3) Possession of such dangerous drug except where obtained through legitimate channels, and except for personal use by the possessor or a member of his household or for administration to an animal owned by him or a member of his household.

Violation of any of the above provisions is subject to the same penalties as are prescribed for other violations of the Food and Drug Act; namely up to 1 year imprisonment or $1,000 fine, or both, for a first offense and up to 3 years imprisonment or up to $10,000 fine, or both, for a second or subsequent offense, or for a first offense committed with intent to defraud or mislead. Higher penalties are prescribed for illegal sales of controlled drugs to minors.

The reported bill follows the recommendations of the administration, and makes all offenses involving illegal trafficking in controlled barbiturates, amphetamines, or hallucinogens a felony, subject to imprisonment of up to 5 years, or a fine of up to $10,000, or both. In case of a sale to a minor by a person over the age of 18, the penalties prescribed in the bill are up to 10 years' imprisonment for a first offense or a fine of not more than $15,000, or both, and in the case of a second or subsequent offense, imprisonment for more than 15 years or a fine of not more than $20,000, or both.

[p. 8]

SECTION-BY-SECTION SUMMARY OF THE COMMITTEE AMENDMENTS

Revision of penalties for offenses involving depressant or stimulant drugs

Section 3 of the legislation makes a general revision in the penalties prescribed in section 303 of the act for offenses involving depressant or stimulant drugs. Examples of such offenses are the unlawful manufacturing, sale, and possession of those drugs, and failure to comply with recordkeeping, plant inspection, and prescription requirements.

The penalties under existing law are as follows:

(1) A first offense involving a depressant or stimulant drug committed without the intent to defraud or mislead is a misdemeanor punishable by a fine not exceeding $1,000 or imprisonment for not more than a year, or both. [p. 9]

(2) A second or subsequent offense or one committed with the intent to defraud or mislead is a felony punishable by a fine not exceeding $10,000 or imprisonment for not more than 3 years, or both.

(3) There is an exception to the provisions described in the preceding paragraphs. If a person 18 or over sells or otherwise unlawfully disposes of a depressant or stimulant drug to a person under 21, the penalty for the first offense is a fine not exceeding $5,000 or imprisonment for not more than 2 years, or both, but if the offense is committed with the intent to defraud or mislead, the penalty would be the one described in paragraph (2). The penalty for second or subsequent offenses is a fine not exceeding $15,000 or imprisonment for not more than 6 years, or both.

The legislation makes the following changes:

(1) In general, if the offense involves the unlawful manufacturing of, sale or other disposal of, or possession with intent to sell, a depressant or stimulant drug or involves counterfeit depressant or stimulant drugs, the penalty (prescribed in the new sec. 303(b)(1) of the act) is a fine not exceeding $10,000 or imprisonment for not more than 5 years, or both.

(2) A stiffer penalty is provided in the new section 303(b)(2) of the act for unlawful sales or other disposals or depressant or stimulant drugs by persons over 18 to persons under 21. The penalty for the first offense is a fine not exceeding $15,000 or imprisonment for not more than 10 years, or both. The penalty provision for second or subsequent offenses increases the maximum fine to $20,000 and the maximum imprisonment to 15 years.

(3) The penalty in the new section 303(b)(3) for possession of a depressant or stimulant drug for purposes other than sale or

other disposal is a fine not exceeding $1,000 or imprisonment for not to exceed 1 year, or both in the case of a first or second offense. The penalty for a third or subsequent offense for such possession would be a maximum fine of $10,000 and maximum imprisonment of 3 years, or both. A special provision is included for a person whose conviction for such possession is his first conviction for any offense under the act. The court may suspend the imposition or execution of sentence on that person and place him on probation for not to exceed 1 year. If the court unconditionally discharges that person from probation prior to the prescribed probation period or if he completes his probation period without violating any of the conditions of his probation, the conviction of that person is automatically set aside. This provision is similar to provisions in the Federal Youth Corrections Act (18 U.S.C. 5005–5026).

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PENALTIES

[SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine: *Provided, however,* That any person who, having attained his eighteenth birthday, violates section 301(q)(2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his twenty-first birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than $5,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than $15,000, or both such imprisonment and fine.

[(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall (except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses) be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.]

SEC. *303 (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.*

(b) (1) Any person who violates clause (1), (2), or (3)(A) of section 301(q), or violates, with respect to a depressant or stimulant drug, any of the provisions of paragraph (3) of section 301 (i), shall, except as otherwise provided in paragraph (2) of this subsection, be imprisoned for not more than five years or fined not more than $10,000, or both.

(2) Any person eighteen or older who violates clause (2) of section 301 (q) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who is under twenty-one, shall be imprisoned for not more than ten years or fined not more than $15,000, or both, except that if any person commits such a violation after a conviction of him under this paragraph has become final, he shall be imprisoned for not more than fifteen years or fined not more than $20,000, or both.

(3)(A) Except as otherwise provided in this subparagraph or in subparagraph (B), any person who violates clause (3)(B) of section 301(q) shall be imprisoned for not more than one year or fined not more than $1,000, or both. If any person commits such a violation after two prior convictions of him for violation of such clause have become final, he shall be imprisoned for not

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more than three years or fined not more than $10,000, or both.

(B) In the case of any person who is convicted for the first time of violating a provision of section 301(q) and whose conviction was for violating clause (3)(B) of such section, the court may suspend the imposition or execution of sentence and place such person on probation subject to such conditions as the court may impose and for such period, not to exceed one year, as the court may prescribe. The court may, in its discretion, unconditionally discharge such person from probation prior to the expiration of the maximum period prescribed for such person's probation. Such discharge shall automatically set aside the conviction, and the court shall issue to such person a certificate to that effect. If during the period of his probation such person does not violate any of the conditions

of his probation, his conviction shall at the expiration of such period be automatically set aside, and the court shall issue to such person a certificate to that effect.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d) that such article is not an article which may not, under the provisions of section 404 or 405, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

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1.13g (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 1958, 90th Cong., 2d Sess. (1968)

INCREASING PENALTIES FOR UNLAWFUL ACTS INVOLVING LSD AND OTHER DEPRESSANT AND STIMULANT DRUGS

OCTOBER 9 (legislative day, OCTOBER 8), 1968.—Ordered to be printed

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MR. STAGGERS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 14096]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendments of the Senate numbered 1, 2, 3, 4, and 5, and agree to the same.

HARLEY O. STAGGERS,
JOHN JARMAN,
PAUL G. ROGERS,
DAVID E. SATTERFIELD III,
W. L. SPRINGER,
ANCHER NELSEN,
TIM LEE CARTER,
Managers on the Part of the House.

LISTER HILL,
RALPH W. YARBOROUGH,
HARRISON WILLIAMS,
CLAIBORNE PELL,
EDWARD KENNEDY,
J. JAVITS,
GEORGE MURPHY,
PETER H. DOMINICK,
Managers on the Part of the Senate.

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STATEMENT OF THE MANAGERS ON THE PART OF THE HOUSE

The managers on the part of the House to the conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes, submit the following statement in explanation of the effect of the action agreed upon by the conferees and recommended in the accompanying conference report:

Amendment No. 1: This amendment changes the penalty provided in the House bill for convictions for the unlawful possession for personal use of depressant or stimulant drugs. The House bill provided a penalty of imprisonment for not more than 1 year, or a fine of not more than $1,000, or both, if there had been no previous conviction for violations of section 301(q) of the Federal Food, Drug, and Cosmetic Act (relating to certain unlawful acts involving depressant or stimulant drugs), and imprisonment for not more than 3 years, or a fine of not more than $10,000, or both, if there was a previous conviction for violating such section. The Senate amendment provided a penalty of imprisonment for not more than 1 year, a fine of not more than $1,000, or both, for the first two convictions for such unlawful possession (irrespective of any prior convictions for violations of such section 301(q)), and provided a penalty of imprisonment for not more than 3 years, a fine of not more than $10,000, or both, for subsequent convictions for such unlawful possession. The House recedes.

Amendment No. 2: This amendment makes certain provisions of the Federal Food, Drug, and Cosmetic Act relating to depressant or stimulant drugs, their containers, and the equipment used to manufacture, compound, or process them applicable to the Canal Zone. The House recedes.

Amendments Nos. 3 and 4: These amendments are conforming amendments to amendment No. 2. The House recedes.

Amendment No. 5: This amendment amends the act establishing the National Eye Institute in the National Institutes of Health by changing the name of the National Institute of Neurological Diseases and Blindness to the National Institute of Neurological Diseases and Stroke. The House recedes.

HARLEY O. STAGGERS,
JOHN JARMAN,
PAUL G. ROGERS,
DAVID E. SATTERFIELD III,
W. L. SPRINGER,
ANCHER NELSEN,
TIM LEE CARTER,
Managers on the Part of the House.

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1.13g (4) CONGRESSIONAL RECORD, VOL. 114 (1968)

1.13g (4) (a) July 12: Amended and passed House, pp. 21032–21040

INCREASING PENALTIES FOR UNLAWFUL ACTS INVOLVING LSD AND OTHER DEPRESSANT AND STIMULANT DRUGS

Mr. STAGGERS. Mr. Speaker, I ask unanimous consent that the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to prescribe penalties for the possession of LSD and other hallucinogenic drugs by unauthorized persons, be considered in the House as in the Committee of the Whole.

The Clerk read the title of the bill.

The SPEAKER. Is there objection to the request of the gentleman from West Virginia?

There was no objection.

The Clerk read the bill, as follows:

H.R. 14096

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) (1) section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end thereof the following new paragraph:

"(w) The term 'hallucinogenic drug' means lysergic acid diethylamide or any other depressant or stimulant drug which the Secretary, after investigation, has found to have, and by regulation designates as having, hallucinogenic properties similar to those of lysergic acid diethylamide. The provisions of subsections (e), (f), and (g) of section 701 shall apply to and govern proceedings for the issuance, amendment, or repeal of regulations under this paragraph."

(2) Section 511(g)(1) of such Act (21 U.S.C. 360a(g)(1)) is amended (A) by inserting "or under section 201(w)" immediately after "section 201(v)" the first time it appears in such section, and (B) by inserting "or pursuant to section 201(w)" immediately after "section 201(V)" the second time it appears in such section.

(b) Section 511 (c) of such Act (21 U.S.C. 360a(c)) is amended—

(1) by inserting "other than a hallucinogenic drug)" immediately after "depressant or stimulant drug" in the first sentence;

(2) by striking out in the second sentence "of this subsection" and inserting in lieu thereof "of the preceding sentence"; and

(3) by adding at the end thereof the following new sentence: "No person, other than a person described in subsection (a) or subsection (b)(2), shall possess any hallucinogenic drug; except pursuant to a prescription by a duly licensed practitioner."

With the following committee amendment:

Strike out all after the enacting clause and insert:

"That section 201(v)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by striking out 'any drug' and inserting in lieu thereof 'lysergic acid diethylamide and any other drug'.

"SEC. 2. (a) Section 511(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a (c)) is amended to read as follows:

" '(c) No person, other than a person described in subsection (a) or (b)(2) of this section, shall—

" '(1) possess any depressant or stimulant drug for sale, delivery, or other disposal to another, or

" '(2) otherwise possess any such drug unless such drug was obtained directly, or pursuant to a valid prescription, from a practitioner (licensed by law to prescribe or administer such drug) while acting in the course of his professional practice.'

"(b) Clause (3) of paragraph (q) of section 301 of such Act (21 U.S.C. 331(q)(3)) is amended to read as follows: '(3)(A) the possession of a drug in violation of section 511(c)(1), or (B) the possession of a drug in violation of section 511(c)(2);'.

"SEC. 3. Section 303 of such Act (21 U.S.C. 333) is amended by striking out subsections (a) and (b) and inserting in lieu thereof the following new subsections:

" 'SEC. 303. (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

" '(b)(1) Any person who violates clause (1), (2), or (3)(A) of section 301(q), or violates, with respect to a depressant or stimulant drug, any of the provisions of paragraph (3) of section 301(i), shall, except as otherwise provided in paragraph (2) of this subsection be imprisoned for not more than five years or fined not more than $10,000, or both.

" '(2) Any person eighteen or older who violates clause (2) of section 301(q) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who is under twenty-one, shall be imprisoned for not more than ten years or fined not more than $15,000, or both, except that if any person commits such a violation after a conviction of him under this paragraph has become final, he shall be imprisoned for not more than fifteen years or fined not more than $20,000, or both.

" '(3)(A) Except as provided in subparagraph (B) of this paragraph, any person who violates clause (3)(B) of section 301(q) shall (1) be imprisoned for not more than one year or fined not more than $1,000, or both, if he has not been convicted of violating any provision of section 301(q) prior to his conviction for violating such clause, or (2) be imprisoned for not more than three years or fined not more than $10,000, or both, if he has been convicted of violating a provision of such section prior to his conviction for violating such clause.

" '(B) In the case of any person who is convicted for the first time of violating a provision of section 301(q) and whose conviction was for violating clause (3)(B) of such section, the court may suspend the imposition or execution of sentence and place such person on probation subject to such conditions as the court may impose and for such period, not to exceed one year, as the court may prescribe. The court may, in its discretion, unconditionally discharge such person from probation prior to the expiration of the maximum period prescribed for such person's probation. Such discharge shall automatically set aside the conviction, and the court shall issue to such person a certificate to that effect. If during the period of his probation such person does not violate any of the conditions of his probation, his conviction shall at the expiration of such period be automatically set aside, and the court shall issue to such person a certificate to that effect.'

"SEC. 4. It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse.

"SEC. 5. The amendments made by this Act shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act committed after the date of the enactment of this Act."

Mr. STAGGERS (during the reading). Mr. Speaker, I ask unanimous consent that the committee amendment be considered as read, printed in the RECORD, and open to amendment at any point.

The SPEAKER. Is there objection to the request of the gentleman from West Virginia?

There was no objection.

Mr. STAGGERS. Mr. Speaker, I move to strike the last word.

Mr. Speaker, the bill before the House today is intended to strengthen the laws against drug abuse which is one of the most serious health problems facing the United States today.

In recent years, the abuse of amphetamines, barbiturates, and hallucinogens such as LSD and the like has increased a great deal particularly among the young.

The bill fundamentally does two things. First, it increases substantially the penalties for illegal trafficking in drugs covered by the Drug Abuse Control Amendments of 1965, and second, it makes possession of these drugs for one's own use a misdemeanor in the case of the first offense, and a felony for the second and subsequent offenses.

In general, people who abuse drugs take them as a means of escape. For one reason or another they cannot face the world they live in without some kind of a crutch and tend to turn to drugs for that crutch, frequently with serious adverse effects on their health. There is also some abuse of drugs by persons who are merely experimenting with them. Sometimes the experimenters do no more than just that; sometimes however, they damage their health in the process.

Drug abuse is a serious problem in our society, and those who cater to this market are among the lowest types of human beings.

With respect to pushers, this legislation provides greatly strengthened penalties. Existing law provides that for a first offense of manufacturing or selling drugs subject to control under the Food and Drug Act, the penalty is 1 year imprisonment and a $1,000 fine, and for a second offense the penalty is 3 years and $10,000. The bill increases these penalties to provide for up to 5 years imprisonment and $10,000 fine [p. 21032] or both for illegal trafficking in these drugs.

As an aid to law enforcement, the bill also makes possession of these drugs obtained without a valid prescription, a criminal offense. A first offender against the possession prohibition will be guilty of a misdemeanor with possible imprisonment up to 1 year and a fine of up to $1,000. A second or subsequent violation of the possession prohibition will lead up to 3 years imprisonment or up to $10,000 fine, or both.

Unfortunately, there is fairly widespread abuse of drugs among the young. During our hearings it was pointed out that in one high school in the United States, a survey indicated that over 8 percent of the students had tried LSD. Now, no one wants to put high school students in jail and, similarly, no one wants to take college students and other young people who may be just experimenting a time or two and throw them into jail. For that reason, our committee put a provision in the bill to the effect that where a person is convicted for a first offense of possession of one of these drugs for his own use, the court may suspend any sentence and place the offender on probation for up to 1 year. If the offender fully complies with the terms and conditions of his probation, his conviction will be automatically set aside so that he does not thereby obtain a criminal record.

Mr. Speaker, drug abuse is a serious problem in America today and our committee has reported a bill to the House that we believe will go a long way toward curbing this problem.

I urge my colleagues to support the bill as reported.

* * * * *

Mr. ROGERS of Florida. Mr. Speaker, I move to strike the requisite number of words.

Mr. Speaker, last November 20 I was joined by 23 of my colleagues on the Interstate and Foreign Commerce Committee in sponsoring a bill to make possession of LSD and other hallucinogenic drugs by unauthorized persons a Federal crime.

At the time I was shocked to learn that with all the work the Congress has done in the field of food, drugs, and cosmetics, there was no Federal penalty prescribed for the use of lysergic acid diethylamide, better known as

LSD, or other hallucinogenic drugs by persons who have obtained the drug illegally.

There are existing penalties for the unauthorized manufacture, distribution, and selling of the drug, yet no penalty for its use.

Thus, there existed a dilemma for the law enforcement officers; they would have ample evidence to conduct a raid where marijuana and LSD were being used. They could arrest those who were smoking marijuana, but they could not arrest those who had taken LSD, or who had LSD in their possession for their own use, unless proof was available to link those possessing LSD with another person who illegally manufactured, distributed, or sold the drug to those possessing it at the time of the raid.

Mr. Speaker, the bill before the House today will correct that gap in the law.

This bill, H.R. 14096, which I introduced, with amendments we adopted in committee, increases the penalties for persons who deal illegally in stimulant, depressant, and hallucinogenic drugs. The bill makes possession of such drugs a misdemeanor on the first [p. 21033] offense unless the drugs in question were obtained pursuant to a valid prescription. Second and subsequent offenses would be a felony.

* * * * *

This bill would prescribe penalties for abuse of the so-called dangerous drugs: Non-narcotic drugs that are habit forming or have a potential for abuse because of their stimulant, depressant, or hallucinogenic effect.

The hallucinogens vary in their chemical makeup, but the most widely known is LSD, lysergic acid diethalymide. Others include peyote, Mescaline, and Psilocybin.

By this bill, LSD is specifically included in section 201(v)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) as well as any other drug which contains any quantity of a substance which now the Attorney General of the United States after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its hallucinogenic effect.

The Attorney General also has the benefit of a drug advisory committee which can offer assistance and recommendations concerning the stimulant, depressant or hallucinogenic effect of existing drugs, or any new drugs which may be manufactured.

There is ample time and proper procedure for objection to the Attorney General's ruling on a specific drug, and such ruling is to be printed in the Federal Register.

* * * * *

The penalties prescribed in the bill are realistic, and were formulated after extensive deliberation by the subcommittee after hearing all the testimony.

We do not wish to make criminals out of a half million high school students in the Nation who may take LSD on one occasion.

But, we do not wish to condone such acts.

This bill strikes a balance.

This bill makes possession of dangerous drugs a misdemeanor on the first offense subject to imprisonment up to 1 year, and a fine up to $1,000.

However, the bill also provides that where an individual is charged with simple possession of dangerous drugs obtained without a doctor's prescription, and he has not previously been convicted of a violation of the law with respect to dangerous drugs, the court may, in lieu of a fine or imprisonment, place the person upon probation for a period, up to 1 year, as the court might determine, subject to such conditions as the court may impose, such as required psychiatric treatment.

[p. 21034]

Mr. BROWN of Ohio.

* * * * *

Without this law, possession and use or sale would still be legal although sale was not permitted. My original proposal would have made felonies possession as well as use. The bill on which we are voting today, however, makes first offense possession only a misdemeanor. [p. 21035]

Mr. HALPERN. Mr. Speaker, it is high time that we faced up to the reality of the dangers of LSD and other hallucinogenic drugs and enacted tough penalties for their possession. As a sponsor of similar legislation, I am gratified to note that the bill before us today fills the enforcement vacuum that has heretofore existed.

This bill provides strong penalties for trafficking in these dangerous drugs. It is my hope that these penalties will act as effective deterrents to both the clandestine manufacturer and his crony, the despicable dope pusher.

The plight of the individual drug user, however, presents an entirely different problem. I am pleased to call to your attention that this difficult situation is handled in H.R. 14096 in a most constructive manner, as I shall point out. The bill makes possession of dangerous hallucinogenic drugs legal only when such drugs are given to a person by a practitioner authorized to dispense them, or upon the legal order for such drugs, as represented in the form of a prescription from a medical practitioner.

Since hallucinogenic drugs are not available through normal channels of distribution, the possession of LSD and similar drugs will, in most cases, be illegal, and subject the possessor to fine or imprisonment. Under present Federal law, Federal authorities may seize any quantity of such drugs from an individual as contraband items obtained from illegal sources, but no action may be taken with respect to the possessor himself where the drugs are for his personal use.

Under the legislation before us today, however, possession of depressant or stimulant drugs for the purpose of sale or other disposal is subject to tough penalties. Simple possession is made illegal, but in the case of a first conviction for any offense under the food and drug law, the court may suspend sentencing, and place the offender on probation which may not exceed 1 year. Thus there is a humanitarian aspect to this tough bill. If the individual completes his probation satisfactorily, or is otherwise unconditionally discharged from his probation period by the court, the conviction will be set aside.

Mr. Speaker, there can be no doubt that this legislation deals effectively with the hallucinogenic-drug abuse problem that exists in our society today. The members of the Interstate and Foreign Commerce Committee are to be congratulated for the intelligent manner in which they have approached this grave, nevertheless delicate problem. They have acted with force, yet, at the same time, have acted humanely, for the bill they have presented to us strikes a balance between varying enforcement and medical viewpoints about how to deal with drug abuse wisely.

I urge the unanimous approval of this bill.

Mr. MACHEN. Mr. Speaker, I rise today to give my full support to H.R. 14096. We have needed legislation prescribing stringent penalties for the unauthorized possession of LSD and other hallucinogenic drugs for some time. The penalties provided in the bill we are now considering are stringent enough to be a great aid to law enforcement officials in cutting off this drug traffic. They will also serve to make it clear that possession of these drugs is not fashionable and counter the idea that seems to have developed among some of our young people that abuse of these drugs is not detrimental to them because there was no penalty for their unauthorized possession.

[p. 21036]

Mr. WIDNALL.

* * * * *

This bill, therefore, strikes a balance between differing points of view on the imposition of penalties for possession of dangerous drugs. Strict penalties are provided for possession, both as an aid to law enforcement and as a deterrent. At the same time, however, a first offender of the prohibition against mere possession may, in lieu of fine or imprisonment, be placed on probation by the court for no longer than a year. The court may prescribe the terms of this probation such as the obtaining of psychiatric help, and following the completion of the probationary period, the conviction is automatically set aside to eliminate any criminal record.

The SPEAKER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER. The question is on the passage of the bill.

The question was taken; and the Speaker announced that the ayes appeared to have it.

Mr. SPRINGER. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that quorum is not present.

The SPEAKER. Evidently a quorum is not present.

The Doorkeeper will close the doors, the Sergeant at Arms will notify absent Members, and the Clerk will call the roll.

The question was taken and there were—yeas 320, nays 2, not voting 111, as follows:

* * * * *

[p. 21040]

1.13g (4) (b) Oct. 4: Amended and passed Senate, pp. 29633, 29634

AMENDMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 1598, H.R. 14096, which I understand can be disposed of briefly.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide—LSD—and other depressant and stimulant drugs, and for other purposes.

The PRESIDING OFFICER. (Mr. HART in the chair). Is there objection to the request of the Senator from Montana?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare, with amendments on page 3, after line 18, strike out:

(3)(A) Except as provided in subparagraph (B) of this paragraph, any person who violates clause (3)(B) of section 301(q) shall (1) be imprisoned for not more than one year or fined not more than $1,000, or both, if he has not been convicted of violating any provision of section 301(q) prior to his conviction for violating such clause or (2) be imprisoned for not more than three years or fined not more than $10,000, or both if he has been convicted of violating a provision of such section prior to his conviction for violating such clause.

And in lieu thereof, insert:

(3)(A) Except as otherwise provided in this subparagraph or in subparagraph (B), any person who violates clause (3)(B) of section 301(q) shall be imprisoned for not more than one year or fined not more than $1,000, or both. If any person commits such a violation after two prior convictions of him for violation of such clause have become final, he shall be imprisoned for not more than three years or fined not more than $10,000, or both.

On page 5, after line 3, insert a new section, as follows:

SEC. 4. (a) Section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)) is amended by striking out the period

at the end thereof and inserting in lieu thereof the following: "; except that such term includes the Canal Zone for the purposes of sections 201, 301(i), 301(p), 301(q), 302, 303, 304 (other than paragraph (1) of subsection (a)), 307, 510, 511, 702, 703, 704, and 705 as they apply to depressant or stimulant drugs, containers thereof and equipment used in manufacturing, compounding or processing any such drug."

(b) Section 304(a) of such Act (21 U.S.C. 334(a)), is amended by inserting "or United States court of a Territory" after "district court of the United States" wherever these words occur.

At the beginning of line 18, change the section number from "4" to "5"; and on page 6, at the beginning of line 3, change the section number from "5" to "6".

Mr. HILL. Mr. President, I have the honor to submit to the Senate H.R. 14096 to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving LSD and depressant and stimulant drugs. This legislation was approved in the House of Representatives by a vote of 319 yeas and 2 nays. The Committee on Labor and Public Welfare approved H.R. 14096 without a dissenting vote.

Mr. President, under existing law it is illegal for unauthorized persons to [p. 29633] manufacture, sell, deliver, or otherwise dispose of certain hallucinogenic, stimulant, and depressant drugs and to possess such drugs for other than personal use. The penalty for a first offense is a maximum fine of $1,000 or imprisonment for not more than 1 year or both such fine and imprisonment; H.R. 14096 would increase the maximum fine to $10,000 and extend the period of imprisonment to not more than 5 years. In the case of a conviction for a second or subsequent offense, the present penalty is a maximum fine of $10,000 or imprisonment for not more than 3 years, or both such fine and imprisonment; H.R. 14096 would increase the maximum term of imprisonment to 5 years.

There is an exception to the penalties described above in the case of an individual 18 years of age or older selling or otherwise disposing of a dangerous drug to someone who is under 21 years of age. The penalty for a first offense is a maximum fine of $5,000 or imprisonment for not more than 2 years, or both; H.R. 14096 would increase the maximum fine to $15,000 and the term of imprisonment to a maximum of 10 years. For a second or subsequent offense, the penalty is a maximum fine of $15,000 or imprisonment of up to 6 years, or both; H.R. 14096 would increase the fine to $20,000 and the maximum imprisonment to 15 years.

Under existing law it is legal for an individual to have dangerous drugs in his possession for use by himself, a member of his household, or an animal of the household. H.R. 14096 would require a valid prescription from a licensed practitioner for such possession. The penalty for a first offense or a second offense would be a maximum fine of $1,000 or imprisonment, for up to 1 year, or both. H.R. 14096 specifies that a court may suspend sentence and place the individual on probation in the case of a first conviction. For a third offense, and subsequent offenses, the maximum fine would be $10,000 and the maximum period of imprisonment would be 3 years.

The enactment of this legislation that is recommended by the Department of Justice is essential if we are to effectively combat the increasing illegal traffic in dangerous drugs.

Mr. President, I ask unanimous consent that the committee amendments be considered en bloc.

The PRESIDING OFFICER. Without objection, the amendments are considered and agreed to en bloc.

The bill is open to further amendment.

Mr. HILL. Mr. President, I send to the desk an amendment and ask that it be stated.

It has seen the devastating effects of heroin among young people who live in the slums of our large cities.

It has studied the so-called "nice drugs," the amphetamines and barbiturates which are used and abused in the affluent suburbs.

More recently, we held hearings on marihuana smoking among college students.

And it was this subcommittee which in 1965 first considered the need for new controls over LSD and the other hallucinogenic drugs.

In that connection, I want to point out a few things about this bill which will increase the penalties for unlawful acts involving LSD and the other dangerous drugs covered under the Federal Food, Drug, and Cosmetic Act.

Mr. President, there is wide agreement that the drug problem is growing more serious every day.

Last year in California alone arrests of young people for marihuana violations increased 180 percent.

There was a reported 400-percent growth in drug arrests in Baltimore, Md.

And there appears to have been a similar upsurge of drug abuse in other parts of the country.

While there has been a decrease in the use of LSD there is an opposite trend with respect to marihuana and we have been told that some 20 percent of our college students have used marihuana.

We have also been told that in several areas of the country, as many as 75 percent of high school students have smoked marihuana.

The PRESIDING OFFICER. The amendment will be stated.

The legislative clerk read as follows:

On page 6, after line 6, insert a new section, as follows:

"SEC. 7. The last sentence of Public Law 90-489 is amended to read as follows: 'The name of the National Institute of Neurological Diseases and Blindness is hereby changed to the 'National Institute of Neurological Diseases and Stroke.' "

Mr. HILL. Mr. President, this amendment is needed to correct a technical error in Public Law 90-489 that changed the name of the National Institute of Neurological Diseases and Blindness. Since that act created a National Eye Institute there is no longer any need for a reference to blindness in the title of the National Institute of Neurological Diseases and Blindness. My amendment, therefore, would change the name of the institute to the National Institute of Neurological Diseases and Stroke. This new title will give recognition to the research effort of the Institute against stroke, a health problem that causes 200,000 deaths each year.

The PRESIDING OFFICER. The question is on agreeing to the amendment of the Senator from Alabama [Mr. HILL].

The amendment was agreed to.

The PRESIDING OFFICER. The bill is open to further amendment. If there be no further amendment to be proposed, the question is on the engrossment of the amendments and third reading of the bill.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time, and passed. [p. 29634]

1.13g (4) (c) Oct. 11: House agrees to conference report, pp. 30761, 30762

INCREASING PENALTIES FOR UNLAWFUL ACTS INVOLVING LSD AND OTHER DEPRESSANT AND STIMULANT DRUGS

Mr. FRIEDEL. Mr. Speaker, I call up the conference report on the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act, to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes, and ask unanimous consent that the statement of the managers on the part of the House be read in lieu of the report.

The Clerk read the title of the bill.

The SPEAKER. Is there objection to the request of the gentleman from Maryland?

There was no objection.

The Clerk read the statement.

The conference report and statement are as follows:

* * * * *

[p. 30761]

Mr. FRIEDEL. (during the reading). Mr. Speaker, I ask unanimous consent that further reading of the statement of the managers on the part of the House be dispensed with.

The SPEAKER. Is there objection to the request of the gentleman from Maryland?

There was no objection.

Mr. ROGERS of Florida. Mr. Speaker, the conference report being considered by the House today is on a bill passed by the House unanimously on July 12 increasing penalties for unlawful acts involving LSD and other depressant or stimulant drugs.

The House bill provided that possession of drugs subject to controls under the legislation is unlawful except where those drugs have been obtained pursuant to a valid prescription. The House bill provided that a first offense of unlawful possession should be a misdemeanor with the second and all subsequent offenses constituting a felony. The Senate amended the bill to provide that both the first and second offenses of unlawful possession should be misdemeanors with the third and subsequent offenses constituting a felony.

Another of the amendments of the Senate makes the laws relating to depressant or stimulant drugs applicable in the Canal Zone.

The final Senate amendment would change the name of the "National Institute for Neurological Diseases" to the "National Institute of Neurological Diseases and Stroke".

Mr. Speaker, the Senate conferees were quite persuasive in their arguments for the approach of the bill, as amended by the Senate. Therefore, the Senate amendments, and we recommend that the House adopt the conference report.

Mr. NELSEN. Mr. Speaker, some time ago this House passed H.R. 14096 to provide a criminal penalty for possession of LSD and similar drugs and to increase penalties for selling them. The Senate changed our bill in only one respect and that was to make the first two convictions for possession misdemeanors rather than only the first violation. The purposes of this amendment to the Drug Act seem to be accomplished by either version and so your conferees receded.

Another entirely extraneous amendment was tacked on in the other body. This would change the name of the National Institute of Neurological Diseases to the National Institute of Neurological Diseases and Stroke. Your conferees were not in favor of this latter amendment but when it appeared that the very desirable change in the LSD statute would be sacrificed unless it remained, your conferees receded. On balance I recommend that we accept the conference report.

Yet, it became clear from our hearings that in spite of the agreement on the seriousness of the problem there is much less agreement on what to do about it.

There is at least a very basic conflict between the law-enforcement agencies, including the drug law-enforcement agencies, on the one hand and the scientists, researchers, and educators on the other hand as to how the drug abuse situation should be handled.

The first group wants strong laws and rather severe penalties even for simple possession of dangerous drugs, while the other group wants no penalties for possession.

Mr. FRIEDEL. Mr. Speaker, I move the previous question on the conference report.

The previous question was ordered.

The conference report was agreed to.

A motion to reconsider was laid on the table.

[p. 30762]

1.13g (4)(d) Oct. 11: Senate agrees to conference report, pp. 30963–30965.

AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT—CONFERENCE REPORT

Mr. HILL. Mr. President, I submit a report of the committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 14096) to amend the Federal Food, Drug, and Cosmetic Act to increase the penalties for unlawful acts involving lysergic acid diethylamide (LSD) and other depressant and stimulant drugs, and for other purposes. I ask unanimous consent for the present consideration of the report.

The PRESIDING OFFICER. The report will be read for the information of the Senate.

The legislative clerk read the report.

(For conference report, see House proceedings of October 11, 1968, pages 30761-30762, CONGRESSIONAL RECORD.)

The PRESIDING OFFICER. Is there objection to the present consideration of the report?

There being no objection, the Senate proceeded to consider the report.

Mr. HILL. Mr. President, this conference report is signed by all of the conferees on the part of the Senate and by all of the conferees on the part of the House.

As passed by the House, the penalty for a conviction for possesion of a dangerous drug, for purposes other than sale, delivery, or other disposal to another, in the absence of a valid prescription from a licensed practitioner, is imprisonment for up to 1 year or a fine of not more than $1,000, or both, if the individual has not been convicted for a violation under the drug abuse control amendments. If there is a previous conviction, the penalty would be imprisonment for up to 3 years or a fine of not more than $10,000, or both.

The Senate amendment provides that the penalty for such illegal possession of dangerous drugs would be imprisonment for not more than 1 year or a fine of not more than $1,000, or both, except that the penalty would be imprisonment for not more than 3 years or a fine of not more than $10,000, or both, for violations after two prior convictions for such illegal possession have become final. The House receded.

The second Senate amendment carried out the recommendations of the Canal Zone Government and the Department of Justice to make the Canal Zone subject to the provisions of the drug abuse control amendments. The House receded. The House also receded on the third and fourth amendments of the Senate that renumbered two sections of H.R. 14096.

Finally, the fifth Senate amendment corrected a technical error in Public Law 90-489, the legislation that established a National Eye Institute by changing the name of the National Institute of Neurological Diseases and Blindness to "National Institute of Neurological Diseases and Stroke." The House receded.

Mr. DODD. Mr. President, I have some brief comments on the bill that has just emerged from the House-Senate conference to establish new penalties for drug violations.

The Juvenile Delinquency Subcommittee has devoted a great deal of time to the study of drug abuse in the Nation.

Many police officers believe that long sentences are a deterrent to crime, the [p. 30963] scientists believe they increase disrespect toward the law among youth.

The majority of law-enforcement officers believe that severe penalties can keep young people in line, the other side gives evidence that such harsh treatment increases what the scientists call alienation of youth from adults and from the society at large.

Having adopted H.R. 14096 we must still give some recognition to this conflict because we have not solved it with this legislation and we will have to make further efforts to resolve the controversy.

Mr. President, I am convinced today, as I have been for some years that in time the best way to deal with our present narcotic and dangerous drug problem will be a comprehensive review of our entire framework of drug laws with a view to making sweeping revisions in these laws.

At this late hour of the 90th Congress, such action cannot be accomplished.

Therefore, I have supported the bill before us, but only in anticipation of a review of all our drug laws in the near future, and in anticipation of the development of a more adequate system of drug laws and drug control procedures.

Having studied the drug issue for a number of years, I have strong views on this matter.

For one, I cannot support the position of the witnesses who have testified before our committee in behalf of more punitive drug laws and longer sentences.

I think today we are compiling sufficient evidence that it is not the length of the penal sentence which restrains a potential lawbreaker, but it is rather the certainty of apprehension and punishment. A recent study conducted in California substantiates this conclusion. And our criminologists and experts on the penal system have held this conviction for a good number of years.

On the other hand, neither do I think any of the dangerous drugs, including marihuana, should be legalized or otherwise made available to the public without proper controls in the case of prescriptive drugs and without penalties for violation in the case of all drugs covered under the Food and Drug Act or under any other law.

I think no person should possess marihuana, LSD, or any drug contrary to the provisions of law and not suffer the consequences.

However, such offenses do not necessarily call for a 5- or a 10-year term of imprisonment.

Such severe penalties are presently possible for the possession of marihuana. Yet, they have not prevented the spectacular rise of marihuana abuse.

The bill before us does not deal with marihuana, but rather with LSD and the other drugs covered by the Food, Drug, and Cosmetic Act.

The penalties which it suggests for simple possession are far less severe than in the case of marihuana.

In fact, this bill as passed by the House of Representatives and as adopted in the Senate Labor and Public Welfare Committee, would provide for setting aside of convictions for certain first and second offenses so that no criminal involvement would mar the record of a young person apprehended with LSD or another controlled drug.

I think this is a considerable improvement over the previous versions of this bill which would have made possession offense an unqualified misdemeanor.

For this reason, I supported this bill and refrained from introducing a substitute proposal.

Nevertheless, I believe there is a loophole in this measure which would make some of the penalties it proposes particularly for the transfer of drugs highly inequitable and unjust.

Therefore, I asked Senator HILL to spell out the congressional intent regarding this measure in the accompanying Senate report.

My concern is with those sections of the bill prescribing felony penalties for "selling, delivering, or otherwise disposing of any depressant or stimulant drug."

Indeed I had prepared an amendment that would differentiate between the penalties applicable to the sale of these drugs on the one hand and to the delivery or other disposal on the other hand.

It would have made felony penalties applicable only to the illegal sale or possession for sale or other commercial transfer of drugs. And it would have applied only misdemeanor penalties to other delivery or disposal of these drugs.

Our hearings have confirmed that the main objective of this bill should be to get at the commercial and criminal trafficker who sells these drugs for profit to our citizens and particularly to young people.

I fully agree that we need substantial penalties for these illegal commercial transactions.

But language in the bill dealing with the delivery or other disposal of a drug to another creates a serious problem that should not have been bypassed.

This language going beyond the sale to delivery or other disposal of the control drugs could make felons out of hundreds of thousands of law-abiding citizens.

It can, in fact, throw our system of justice and of law back to the dark ages when men could be hanged for as trivial a crime as picking pockets.

And, if misused, it would, in effect, invade millions of American homes with the threat of a hard and inequitable law. Mr. President, under the provisions spelled out in this legislation, a mother giving one of her own sleeping pills to her daughter could go to prison for 10 years because of an essentially humanitarian act.

If we impose the same penalties for any type of disposal of these drugs to another as we do for the sale of these drugs we, in effect, make a felon out of a college student who gives just one amphetamine pill to a friend to help him stay awake to prepare for an examination. And we make a felon out of any individual who, however unwisely from a medical standpoint, but with the best motivation and without any criminal intent, gives a sleeping pill or a pep pill to a friend.

All these individuals can be subject to a felony record and in many cases to a 10-year prison term under the provisions of this bill.

Certainly, it is not good practice for any layman to give any medicine to another. This should be the prerogative of a physician. Nevertheless, we are dealing with reality here and our hearings prove that this happens every day all over the country among essentially law-abiding people.

Wrong as this may be, I insist that these people are not felons and should not be made such under this law.

Mr. President, I can stand the thought of a young college student facing a misdemeanor charge for passing a pep pill to a friend because the judge can fine him $10 and his conviction may even be expunged. But I think it incredible that such a young person or any of the other persons I have mentioned could be made felons and sent to prison for 10 years because of this relatively trivial crime.

At a time when our system of criminal justice tends to emphasize treatment and rehabilitation, to expand probation, work-release programs, and other noninstitutional correction, it is an incredible paradox to create a new felony offense and threaten perhaps millions of our people, many of them young, many of them our brightest college students.

Ours is a drug-infested society where

prescription drugs and other control drugs are passed from one person to another. But, when no commercial purpose or criminal intent is involved in these transactions they should not be subject to felony convictions because of a catchall phrase in the bill.

Let me emphasize that large variety of the barbiturate- or amphetamine-type drugs have become standard items in millions of medicine cabinets in American homes.

And, I venture to say that in millions of homes these drugs are acquired on prescription by one member of the family but are used by several other members as well.

Under this bill, which was introduced mainly because of the public's fear of LSD, we will now have millions of new felons in the Nation every time medicine cabinets are opened and one member of the family gives a pill with stimulant or depressant properties to another member.

This is what has concerned me about the provisions of this bill. They are acceptable when applied to the traffic in LSD, but they are outrageous if applied across the board to every transfer of a control drug by one person to another, even if the law is not enforced in these instances.

This is why I considered amending the bill to allow felony penalties only for violations in connection with commercial transfer of the drugs controlled by the Food, Drug, and Cosmetic Act.

The Justice Department asked me to withhold the amendment. The Department claims that in many cases, prosecution becomes impossible if a sale or the intent to sell has to be proved.

I am not convinced that this is a legitimate argument. And I will look at it more closely when the Juvenile Delinquency Subcommittee resumes hearings on drug abuse next year.

At this time, however, the Justice Department has given assurance that felony indictments would not be insti- [30964] tuted in cases of noncommercial possession or transfer of small amounts of drugs.

Senator HILL has included that assurance in the language of the report and with that expression of congressional intent in this matter, I think we have achieved some protection against the possibility of inequitable application of the law.

In that light, I think the bill will promote a more effective procedure for controlling the drug menace.

I want to commend the President for offering this bill as a part of his broad crime control program.

I want to commend Senator HILL for his able management of the bill in the Senate.

And, with the qualifications I have outlined, I want to commend this bill to the public as an expression and a part of this administration's active and effective effort to control the serious crime problem in the Nation.

Mr. HILL. Mr. President, I move the adoption of the report.

The PRESIDING OFFICER. The question is on agreeing to the conference report.

The report was agreed to.

[p. 30965]

1.13h COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT

October 27, 1970, P.L. 91–513, Title II, §701(b), 84 Stat. 1281

REPEALS AND CONFORMING AMENDMENTS

SEC. 701. (a) Sections 201(v), 301(q), and 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(v), 331(q), 360(a) are repealed.

(b) Subsections (a) and (b) of the section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) are amended to read as follows:

"SEC. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

[p. 1281]

1.13h (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 91–613, 91st Cong., 1st Sess. (1969)

CONTROLLED DANGEROUS SUBSTANCES ACT OF 1969

DECEMBER 16, 1969.—Ordered to be printed

MR. DODD, from the Committee on the Judiciary, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 3246]

The Committee on the Judiciary, having under consideration legislation to protect the public health and safety by amending the narcotic, depressant, stimulant and hallucinogenic drug laws, and for other purposes, reports an original bill and recommends that it do pass.

NEW PROVISIONS ADDED IN COMMITTEE

The original bill generally follows the basic language and structure of both S. 1895 and S. 2637. However, three major provisions were added to the basic bill in committee which were originally contained in S. 1895. One of these provisions is designed to change the penalty structure applicable to drug offenses under title V. The other provision adds certain tranquilizers to the list of "controlled substances" under title II. And the third provision is designed to establish a committee to study marihuana.

The penalty provision was added based on evidence developed through subcommittee investigations and hearings which indicated that the penalties provided in S. 2637 were inconsistent as compared with the harmfulness, abuse characteristics and their social implications of the several classes of drugs. For example, to impose the same high mandatory penalties for marihuana-related offenses as for LSD and heroin offenses is inequitable in the face of a considerable amount ef evidence that marihuana is significantly less harmful and dangerous than LSD or heroin.

PURPOSE OF THE BILL

[p. 1]

The bill was a necessary reaction to the reorganization of drug control agencies carried out under President Johnson's Administration in 1968. Under the reorganization plan the drug enforcement agencies of the Department of Health, Education, and Welfare and of the Treasury Department (except those involved with customs) were transferred to the Department of Justice.

The next step was to collect the diverse drug control and enforcement laws under one piece of legislation to facilitate law enforcement, drug research, educational and related control activities. Equally, the purpose expressed in the bill is to classify the drugs subject to control in specific schedules according to the chemical properties, psychological and physical effects and abuse potential of the different drugs. Based on this classification, the schedules developed were then made to correspond to the penalties applicable to violations involving the different classes of drugs.

The basic elements of the penalty structure are described in subsequent sections of the report.

Furthermore, the overall purpose of the bill is to improve the administration and regulation of the manufacture, importation and exportation of the controlled dangerous substances covered under its provisions, so that the widespread diversion presently occurring can be halted.

TITLE VII—ENFORCEMENT PROVISIONS

[p. 3]

Under this title, enforcement personnel of the Bureau of Narcotics and Dangerous Drugs are vested with broader enforcement powers required for the effective enforcement of this act.

The title provides for search warrants which allow entry without notice into premises for the purpose of seizing property that might otherwise be destroyed or to protect human life. This is a vital provision to help law enforcement officers obtain evidence for criminal proceedings against traffickers in controlled dangerous substances. The ability to prosecute these offenders often depends on the

[p. 9]

amount of drugs found on the premises. At the same time these substances can be easily destroyed in a relatively short period of time.

Apprehension of the serious traffickers and illicit manufacturers of drugs is probably the most effective way to control the drug problem. The so-called no-knock provision established by this title is an invaluable legal device to help achieve this objective.

It also provides administrative inspections and warrants and criteria for forfeiture of certain property which is substantially involved in drug violations.

It further provides for notification to be given in certain cases to individuals against whom criminal proceedings are to be instituted under this act and for privilege and immunity against self-incrimination for witnesses compelled to testify in proceedings initiated under this act. In addition, it places the burden of proof on a person involved in litigation under the act to rebut the presumption by the Government that such person has violated any registration or recordkeeping requirements. Equally, the title protects Federal enforcement officers from liability for law enforcement activities relating to controlled dangerous substances and provides for the expenditure of certain Federal funds in payment to persons giving information concerning violations of the act.

[p. 10]

TITLE VII—ENFORCEMENT PROVISIONS

Section 701. Powers of Enforcement Personnel

Section 701(a) incorporates and expands upon 21 U.S.C. 372(c) and 26 U.S.C. 7607, Section 372(e) contains the authority granted to agents of the former Bureau of Drug Abuse Control by the Drug Abuse Control Amendment of 1965. Section 7607 contains the authority granted to agents of the former Bureau of Narcotics.

The authorities in each of the above sections have been carried over by proposed section 701(a) of this act. These authorities have the right to carry firearms, execute and serve search-and-arrest warrants, subpenas, and summonses. This authority is expanded to include the execution and service of administrative inspection warrants. This additional authority is necessary to conform to the Supreme Court decisions in the *Camara* and *See* cases which require the Government to obtain warrants to make inspections—that is, accountability investigations.

Both 21 U.S.C. 372(e)(4) and 26 U.S.C. 7607(2) granted agents the authority to make arrests for dangerous drug and narcotic drug or marihuana offenses, respectively, committed in the agent's presence or, in the case of felonies, when the agent has probable cause. Section 701(a)(3) broadens this arrest authority to include any offenses against the United States.

Section 701(a)(4) contains the authority to seize property which is in violation of the narcotic and dangerous drug laws.

Section 701(a)(5) grants the agents authority to perform other law enforcement duties as the Attorney General may designate. This section is not aimed at any particular function, but provides the Attorney General with flexibility in the utilization of enforcement personnel.

Subsection (b) of this section provides that nothing shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

[p. 30]

1.13h (2) HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

H.R. REP. No. 91-1444, (Parts 1 & 2), 91st Cong., 2d Sess. (1970)

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

SEPTEMBER 10, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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MR. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 18583]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 18583) to amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment strikes out all after the enacting clause and inserts a new text, which is set forth in italic in the reported bill.

PRINCIPAL PURPOSE OF THE BILL

This legislation is designed to deal in a comprehensive fashion with the growing menace of drug abuse in the United States (1) through providing authority for increased efforts in drug abuse prevention and rehabilitation of users, (2) through providing more effective means for law enforcement aspects of drug abuse prevention and control, and (3) by providing for an overall balanced scheme of criminal penalties for offenses involving drugs.

[p. 1]

PART G—CONFORMING, TRANSITIONAL AND EFFECTIVE DATE, AND GENERAL PROVISIONS

Section 701—Repeals and conforming amendments

Section 701 deletes from the Federal Food, Drug, and Cosmetic Act the provisions relating to depressant or stimulant drugs inserted by the Drug Abuse Control Amendments of 1965, and the 1968 penalty amendments, and makes conforming amendments to the Federal Food, Drug, and Cosmetic Act, section 302(a) of the Public Health Service Act, and sections 1111 and 1952 of title 18 of the U.S. Code. Section 302(a) of the Public Health Service Act, which now requires the Service to investigate the use and misuse of narcotic drugs and advise the Attorney General on the quantities of narcotic drugs necessary to supply U.S. medicinal and scientific requirements, is also broadened so as to require research in drug abuse and drug dependence for all controlled substances and to require the Service to advise the Attorney General on domestic requirements for all such substances.

See, also, sections 1101 and 1102 of the bill with respect to repeals of, and conforming amendments to, laws within the jurisdiction of the Ways and Means Committee.

[p. 58]

PART II

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

SEPTEMBER 10, 1970.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

MR. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

CHANGES IN EXISTING LAW

[To accompany H.R. 18583]

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule III of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) (1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The Term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone [:except that such term includes the Canal Zone for the purposes of sections 201, 301(i), 301(p), 301(q), 302, 303, 304 (other than paragraph (1) of subsection (a)), 307, 510, 511, 702, 703, 704, and 705 as they apply to depressant or stimulant drugs, containers thereof and equipment used in manufacturing, compounding or processing any such drug].

[p. 1]

* * * * * * *

Sec. 303. (a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000 or both.

(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

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1.13h (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 91-1603, 91st Cong., 2d Sess. (1970)

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

OCTOBER 13, 1970.—Ordered to be printed

MR. STAGGERS, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany H.R. 18583]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 18583) to amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its amendments numbered 1, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, and 20.

That the House recede from its disagreement to the amendments of the Senate numbered 2 and 21, and agree to the same.

Amendment numbered 3:

That the House recede from its disagreement to the amendment of the Senate numbered 3, and agree to the same with an amendment, as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

* * * * * * *

[p. 1]

1.13h(4) CONGRESSIONAL RECORD, VOL. 116 (1970)

1.13h (4)(a) Jan. 28: Considered and passed Senate, p. 1690
[No Relevant Discussion on Pertinent Section]

1.13h (4)(b) Sept. 24: Considered and passed House, p. 33667
[No Relevant Discussion on Pertinent Section]

1.13h (4)(c) Oct. 7: Amended and passed Senate, pp. 35496–35497
[No Relevant Discussion on Pertinent Section]

1.13h (4)(d) Oct. 14: House agrees to conference report, p. 36655
[No Relevant Discussion on Pertinent Section]

1.13h (4)(e) Oct. 14: Senate agrees to conference report, p. 36885
[No Relevant Discussion on Pertinent Section]

1.14 RESEARCH AND DEVELOPMENT ACT, CONTRACTS, AS AMENDED

10 U.S.C. §§2353, 2354 (1956)

[Referred to in 42 U.S.C. §241(h)]

THE RESEARCH AND DEVELOPMENT ACT

§ 2353. Contracts: acquisition, construction, or furnishing of test facilities and equipment

(a) A contract of a military department for research or development, or both, may provide for the acquisition or construction by, or furnishing to the contractor of research, developmental, or test facilities and equipment that the Secretary of the military department concerned determines to be necessary for the performance of the contract. The facilities and equipment, and specialized housing for them, may be acquired or constructed at the expense of the United States, and may be lent or leased to the contractor with or without reimbursement, or may be sold to him at fair value. This subsection does not authorize new construction or improvements having general utility.

(b) Facilities that would not be readily removable or separable without unreasonable expense or unreasonable loss of value may not be installed or constructed under this section on property not owned by the United States, unless the contract contains—

(1) a provision for reimbursing the United States for the fair value of the facilities at the completion or termination of the contract or within a reasonable time thereafter;

(2) an option in the United States to acquire the underlying land; or

(3) an alternative provision that the Secretary concerned considers to be adequate to protect the interests of the United States in the facilities.

(c) Proceeds of sales or reimbursements under this section shall be paid into the Treasury as miscellaneous receipts, except to the extent otherwise authorized by law with respect to property acquired by the contractor. Aug. 10, 1956, c. 1041, 70A Stat. 134.

§ 2354. Contracts: indemnification provisions

(a) With the approval of the Secretary of the military department concerned, any contract of a military department for research or development, or both, may provide that the United States will indemnify the contractor against either or both of the following, but only to the extent that they arise out of the direct performance of the contract and to the extent not compensated by insurance or otherwise:

(1) Claims (including reasonable expenses of litigation or settlement) by third persons, including employees of the contractor, for death, bodily injury, or loss of or damage to property, from a risk that the contract defines as unusually hazardous.

(2) Loss of or damage to property of the contractor from a risk that the contract defines as unusually hazardous.

(b) A contract, made under subsection (a), that provides for indemnification must also provide for—

(1) notice to the United States of any claim or suit against the contractor for the death, bodily injury, or loss of or damage to property; and

(2) control of or assistance in the defense by the United States, at its election, of that suit or claim.

(c) No payment may be made under subsection (a) unless the Secretary of the department concerned, or an officer or official of his department designated by him, certifies that the amount is just and reasonable.

(d) Upon approval by the Secretary concerned, payment under subsection (a) may be made from—

(1) funds obligated for the performance of the contract concerned;

(2) funds available for research or development, or both, and not otherwise obligated; or

(3) funds appropriated for those payments. Aug. 10, 1956, c. 1041, 70A Stat. 134.

1.14a ARMED FORCES RESEARCH AND DEVELOPMENT ACT

July 16, 1952, P.L. 82–557, §§4, 5, 66 Stat. 725

SEC. 4. Any contract of the military departments for research or development, or both, may provide for the acquisition or construction by, or furnishing to, the contractor of such research, developmental, or test facilities and equipment as may be determined by the Secretary concerned to be necessary for the performance thereof. Such research, developmental, or test facilities and equipment, including specialized housing therefor, may be acquired or constructed at Government expense, and may be furnished to the contractor by lease, loan, or sale at fair value, and with or without reimbursement to the Government for the use thereof: *Provided,* That nothing contained in this subsection shall be deemed to authorize new construction or improvements having general utility: *Provided further*, That nothing contained herein shall be deemed to authorize the installation or construction of facilities on property not owned by the Government which would not be readily removable or separable without unreasonable expense or unreasonable loss of value, unless adequate provision is made in the contract for (1) reimbursement to the Government of the fair value of such facilities upon the completion or termination of the contract, or within a reasonable time thereafter, or (2) an option in the [p. 725] Government to acquire the underlying land, or (3) such other provisions as will in the opinion of the Secretary concerned be adequate to protect the Government's interest in such facilities: *And provided further*, That all money arising from sales or reimbursement under this section shall be covered into the Treasury as miscellaneous receipts, except to the extent otherwise authorized by law with respect to contractor-acquired property. The Secretary of each of the military departments shall transmit to the Congress reports covering contracts for research or development entered into during each six months following the enactment of this Act. Each such report shall contain (1) a list of each contract for research or development entered into during such period the total cost of which to the Government will exceed $50,000, and (2) specific information with respect to each such contract, except that specific information the disclosure of which he deems incompatible with the security of the United States may be excluded from such reports.

SEC. 5. With the approval of the Secretary concerned, any contract of the military departments for research or development, or both, may provide that the Government will indemnify the contractor against either or both of the following, to the extent that they arise out of the direct performance of said contract and are not compensated by insurance or otherwise: (1) Liability on account of claims (including reasonable expenses of litigation or settlement of such claims) by third persons, including employees of the contractor, for death, bodily injury, or loss of or damage to property, arising as a result of a risk defined in the contract to be unusually hazardous: *Provided*, That any contract so providing shall also contain appropriate provisions for notice to the Government of suits or actions filed or claims made, against the contractor, with respect to any alleged liability for such death, bodily injury, or loss of or damage to property, and for control of or assistance in the defense of any such suit, action, or claims, by the Government, at its election; and (2) loss of or damage to property of the contractor arising as a result of a risk defined in the contract to be unusually hazardous: *And provided further*, That no payment shall be made by the Government under authority of this section unless the amount thereof shall first have been certified to be just and reasonable by the Secretary concerned or by an official of the department designated for such purpose by the Secretary. Any such payment may be made, with the approval of the Secretary concerned, out of any funds obligated for the performance of such contract or out of funds available for research and development work and not otherwise obligated; or out of any funds appropriated by the Congress for the making of such payments.

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1.14a (1) HOUSE COMMITTEE ON ARMED SERVICES

H.R. REP. No. 548, 82nd Cong., 1st Sess. (1951)

FACILITATING THE PERFORMANCE OF RESEARCH AND DEVELOPMENT WORK BY AND ON BEHALF OF THE DEPARTMENTS OF THE ARMY, NAVY, AND AIR FORCE

JUNE 12, 1951.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. HEBERT, from the Committee on Armed Services, submitted the following

REPORT

[To accompany H.R. 1180]

The Committee on Armed Services, to whom was referred the bill (H.R. 1180) to facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

The purpose of the proposed legislation is to provide the armed services with powers which are considered to be necessary to facilitate the carrying on of their research and development programs.

The recent war may truly be called the scientists' war. Of course, the most spectacular evidence of this is the development of the atomic bomb. Other known illustrations are the proximity fuze, the myriad applications of radar, recoilless weapons, and the use of infra-red in front-line combat. On the side of the enemy there were such things as the V–1 guided missile, and the V–2 rocket, the sonic torpedo, and the snorkel submarine.

The significance of this for our national security in the future has been well stated by Dr. Vannevar Bush in his report to the President entitled, "Science—The Endless Frontier":

> We cannot again rely on our allies to hold off the enemy while we struggle to catch up. There must be more—and more adequate—military research in peacetime.

It must be remembered that on mobilization day the enemy will have a far greater number of men under arms than the Allied Nations. The logical answer on our part appears to be an equivalent counter-superiority in arms and equipment as a result of our "more

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—and more adequate—military research in peacetime." The truth of this statement has been demonstrated by the early experience of UN troops against the mass attacks of Communists in Korea.

As a result of that experience, funds have been made available for the acceleration of the research and development program.

Money alone, however, will not enable the military departments to meet their research and development obligations. They must have clear authority necessary to arrange and organize their research and development work so as to secure the maximum results for the funds expended. It is for that reason that the Armed Forces have joined in recommending the passage of H. R. 1180.

This proposal does not require the increase of current appropriations for research and development. The proposed legislation will result in no increased cost to the Government, except to the extent that unforeseen hazards may create liabilities under the indemnity provisions contained in section 5 of the proposed bill. It is impossible to foresee the extent of such claims under these provisions, or even whether justifiable claims will actually be made.

Experience has shown conclusively how research and development, its personnel, and its institutions, must have each of the elements of authority incorporated in this bill. This can be demonstrated by analyzing the bill section by section.

SECTIONAL ANALYSIS

Section 1 provides for the establishment of research and development advisory committees or panels and the employment of such part-time advisory personnel in each of the military departments as they may deem necessary in carrying out their research and development activities. The wartime experience of the armed services has demonstrated that such committees or panels and part-time consultants are of immeasurable aid to the research and development programs of the armed services, because they focus the greatest scientific minds of the country on the planning and execution of the research and development projects of the armed services. The members of these committees or panels and such advisory personnel should be permitted to serve either with or without compensation, and should be exempted from the laws (secs. 281, 283, and 284 of title 18, U. S. Code) which contain certain statutory prohibitions and penalties which would be applicable to all Federal employees, for example, in regard to the participation in Government contracts or claims against the Government. The most competent persons and efficient firms are those we hope will accept appointments and contracts with the Government, and may be in a positon to lay valid claims against the Government. These persons and firms should not be embarrassed by their inter-relationship while in Government service. This section would overcome the reluctance of such persons and firms and put them at ease in accepting such work. Past experience has shown that it is in the best interests of the United States to utilize the experience of the country's outstanding industrialists, scientists, and educators who might be unwilling to accept pay, or fearful of liabilities under the cited laws.

Section 2 authorizes the employment of scientific and technical persons, whether or not they are citizens of the United States. It is [p. 2] common knowledge that many of the leading experts in these fields are noncitizens and this authority will permit the employment of such persons under the provisions of Public Law 600, Seventy-ninth Congress.

Section 3 provides for long-term contracts. Research and development programs must be planned far in advance in order to achieve and maintain superior weapons and equipment systems. The individual projects which contribute to the over-all programs are unpredictable as to results and as to the length of time required for completion. Continuing funds as authorized in Public Law 604, Eighty-first Congress, together with a 5-year contract term plus provision for additional 5-year contract renewals, will provide the necessary continuity. Under the proposed system the Bureau of the Budget and the Congress would not lose control over appropriated funds. In the case of each activity they would be presented annually, with a single figure, representing the "bank balance" of that activity. A large percentage of research and development activities are conducted by contract with civilian institutions. The inability of the military services to conform to established business practices in making long-term contracts seriously impairs this relationship. A prospective contractor hesitates to commit a highly trained staff, recruited with difficulty, for fear of termination of the work when the contract is on a short-term basis. Accelerated progress in critical fields may thus be retarded until a subsequent appropriation to cover an amendment or a new contract can be justified. Authority to place long-term contracts is considered essential to meet the foregoing requirements.

Section 4 provides for the furnishing of necessary research, developmental or test facilities to contractors, subject to adequate protection of the Government's interests therein. It is the committee's understanding that, under the provisions of this section, the military departments may utilize research and development funds for the furnishing or construction of equipment or facilities for the use of contractors where appropriate. Wartime experience indicates that situations arise in which contractors require special facilities for the performance of their contracts. Since in many cases these facilities would be of no use to them apart from the performance of such contracts, they are unable to provide the facilities at their own expense. On the other hand, to permit contract prices to include sufficient amounts to cover the cost of such facilities, would obviously be unfair to the Government in that the Government would, in effect, be not only buying the facilities, but would then leave them in the possession of the contractor. The solution proposed herein is to authorize the Government to provide such facilities, at the same time protecting its interest therein.

Section 5 provides authority for the military departments to agree to indemnify contractors against liability and loss resulting from injury to persons or damage to property arising out of the direct performance of a research and development contract, to the extent that such losses are not compensated by insurance or otherwise. In many cases, contractors are reluctant to undertake a research or development contract involving extremely hazardous new developments without adequate protection in the event of liability resulting from claims made as a result of damage from those experiments. No provision can be made for such protection by in-

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cluding a reserve in the contract price, and the cost of insurance, if at all obtainable, would be prohibitive. The solution is for the Government to agree to indemnify such a contractor, subject to the safeguards provided in this section.

Section 6 provides authority for the Secretaries of the military departments, with the approval of the Secretary of Defense and the

Comptroller General to promulgate regulations stating the extent to which vouchers for funds expended under any research and development contract shall require itemization or substantiation prior to payment. Universities and nonprofit institutions, in which much research is conducted, as well as some commercial organizations, are not equipped to handle the detailed vouchering procedures and auditing technicalities required. Difficulty is experienced in negotiating contracts with these institutions for that reason. Relaxed procedures were applied to contracts let by the Office of Scientific Research and Development during the war and proved highly satisfactory. The requirement of approval by the Secretary of Defense and the Comptroller General is an important safeguard on the extent to which this authority will be used.

Section 7 provides authority for the prompt publication of scientific and technical information developed by the departments, which will be extremely useful in disseminating such information. Frequently, it will be advantageous for the departments to avail themselves of specialized means of distribution of such information, such as the use of the services and mailing lists of appropriate learned societies. The current situation of inflation, increased costs, and the consequent shrinkage in media of publication of scientific work, plus increased scientific activity, has resulted in considerable difficulty in the publication of the findings of scientific work. Scientific progress is directly related to the prompt dissemination of technical data to others who are engaged in similar work. It is to the interest of the military service to assist in such dissemination of information, subject to security controls. This section excludes the publication of such material from the provisions of law which generally require that all printing for Government agencies shall be done at the Government Printing Office.

Section 8 authorizes the Secretaries of the military departments to delegate any authority provided by this act to the Under or Assistant Secretaries of the Departments, the Chiefs of the Technical Services, bureaus or offices, and to one assistant of each such chief. Such delegation of authority is normal and is considered essential in order to achieve the necessary facility and flexibility of operation.

There can be no question that the future security of our Nation depends largely upon our military research and development programs. The purpose of the proposed bill is to provide the armed services with adequate means for properly discharging their research and development functions.

As previously noted, it is impossible to predict unforeseen hazards which may create liabilities under the indemnity provisions contained in section 5 of the proposed bill. It is the intention of the committee that the departments continue the current policy of having contractors insure employees against hazards in doing research contract work where the premiums on such insurance are not prohibitively costly. It is recognized that some of the undertakings in the research and development contracts are so hazardous that they [p. 4] cannot be insured in any amount. If such contracts are to be undertaken, and the committee agrees that they must, there is no other solution than that of having the Government agree to indemnify the contractor if liability should be sustained by him. Except for this possibility, the proposed legislation will result in no increased cost to the Government.

The proposed legislation is a part of the Department of Defense legislative program for 1951 and it has been approved by the Bureau of the Budget. The Department of Defense recommends that it be enacted by the Congress as is evidenced by the report of the Secretary of Defense which is hereto attached and made a part of this report:

ASSISTANT SECRETARY OF DEFENSE
Washington, D.C., January 5, 1951.

Hon. SAM RAYBURN,
Speaker of the House of Representatives.

MY DEAR MR. SPEAKER: There is forwarded herewith a draft of legislation "to facilitate the performance of research and development work by and on behalf of the Army, the Navy, and the Air Force, and for other purposes," together with a sectional analysis thereof.

This proposed legislation is a part of the Department of Defense Legislative Program for 1951 and it has been approved by the Bureau of the Budget. The Department of Defense recommends that it be enacted by the Congress.

Purpose of the legislation: the purpose of this legislation is to provide the military departments with administration authority required to carry out research and development programs. General authority for research and development programs of the Departments of the Army and Air Force is provided by the Army and Air Force Authorization Act of 1949, while the Department of the Navy carries out its research and development program under the authority of the act of August 1, 1946 (60 Stat. 779). The National Security Act of 1947, as amended, provides for the authority of the Secretary of Defense and the Research and Development Board with respect to all research and development programs of the Department of Defense. This legislation is not designed to affect such general authorities and relationships but merely to provide the military departments with administrative powers which are essential, in order to effectively implement the general authority to conduct such programs.

These essential powers are:

(1) The appointment of research advisory committees;
(2) The employment of alien scientists and technicians;

(3) The periodic renewal of research contracts;

(4) The furnishing of Government facilities;

(5) The indemnification against damage loss, where the contractor is unable to procure insurance coverage;

(6) A simplified voucher procedure, the requirements of which can be met by colleges, universities, institutes, and other contractors; and

(7) The publication and dissemination of scientific and technical information.

Legislative references: Legislation similar to this proposal was introduced in the Eightieth Congress (S. 1560). S. 1560 was passed by the Senate (S. Rept. No. 1397), but was not reported out of the House Committee before adjournment.

The Army and Air Force Authorization Act of 1949 (Public Law 604, 81st Cong.) which was approved on July 10, 1950 authorized the Departments of the Army and Air Force to conduct, engage, and participate in research and development programs and to procure or contract for facilities, equipment, services, and supplies to effectuate such programs. That act also provided for the continued availability of appropriations to the Departments of the Army, Navy, and Air Force for research and development.

Legislation identical with this proposal except for technical changes and the omission of authority for the continued availability of appropriations for research and development in the enclosed draft, was included in the Department of Defense legislative program for consideration by the Eighty-first Congress, second session, approved by the Bureau of the Budget, and introduced in the Congress (S. 3521 and H.R. 8352). No further action was taken by the Eighty-first Congress with respect to S. 3521 and H.R. 8352.

Cost and budget data: Enactment of the proposed legislation should result in no additional expenditure of public funds, except to the extent that unforeseen

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hazards may create liabilities under the indemnity provisions of the proposed legislation. It is impossible to foresee the extent of claims under those provisions.

Department of Defense action agency: The Department of the Army has been designated as the representative of the Department of Defense for this legislation.

Sincerely yours,

MARX LEVA.

Existing comparable law is printed below on the left with the bill (H.R. 1180) on the right:

EXISTING COMPARABLE LAW	THE BILL (H. R. 1180)
ARMY AND AIR FORCE AUTHORIZATION ACT OF 1949—RESEARCH AND DEVELOPMENT AUTHORIZATION (Army Authority)	A BILL To facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes:
SEC. 104. The Secretary of the Army is hereby authorized to conduct, engage, and participate in research and development programs related to activities of the Army of the United	That each of the Secretaries of the military departments is hereby authorized to establish such advisory committees or panels as may be necessary for the conduct of the research and

EXISTING COMPARABLE LAW

States and to procure, or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs.

(Air Force Authority)

SEC. 205. The Secretary of the Air Force is hereby authorized to conduct, engage, and participate in research and development programs related to activities of the Air Force of the United States and to procure, or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs.

(Army, Navy, and Air Force Appropriation Authority)

SEC. 303. (a) There are hereby authorized to be appropriated, out of any moneys in the Treasury of the United States not otherwise appropriated, such sums as may be necessary to carry out the purposes of this Act.

(b) Moneys appropriated to the Departments of the Army, Navy, or Air Force for procurement of technical military equipment and supplies, the construction of public works, and for research and development, including moneys appropriated to the Department of the Navy for the procurement, construction, and research and development of guided missiles, which are hereby authorized for the Department of the Navy, shall remain available until expended unless otherwise provided in the appropriation Act concerned.

ACT OF AUGUST 1, 1946 (60 STAT. 779)

(Office of Naval Research)

* * * That there is hereby created and established in the Office of the Secretary of the Navy an Office of Naval Research, which shall be charged with such duties relating to (1) the en-

THE BILL (H. R. 1180)

development activities of his department, and to employ such part-time advisory personnel as they may deem necessary in carying out such activities. Persons holding other offices or positions under the United States for which they receive compensation, while serving as members of such committees, shall receive no additional compensation for such services. Other members of such committees and other part-time advisory personnel so employed may serve without compensation or may receive compensation at a rate not to exceed $50 for each day of service, as determined by the appointing authorities.

Service of an individual as a member of any such advisory committee, or in any other part-time capacity for a department hereunder, shall not be considered as service bringing such individual within the provisions of section 281, 283, or 284 of title 18, United States Code, unless the act of such individual, which by such section is made unlawful when performed by an individual referred to in such section, is with respect to any particular matter which directly involves a department which such person is advising or in which such department is directly interested. The provisions of the Act of July 12, 1870 (Revised Statutes, 3679), as amended shall not apply to the acceptance of voluntary service of any member of any committee or panel authorized by this section.

SEC. 2. No provision of law prohibiting employment of or payment of compensation or expenses to any person not a citizen of the United States shall

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apply to any expert, scientific, technical, or professional person whose appointment or employment in connection with the research and development activities of the military departments is determined by the Secretary concerned to be necessary.

EXISTING COMPARABLE LAW

couragement, promotion, planning, initiation, and coordination, of naval research; (2) the conduct of naval research in augmentation of and in conjunction with the research and development conducted by the respective bureaus and other agencies and offices of the Navy Department; and (3) the supervision, administration, and control of activities within or on behalf of the Department of the Navy relating to patents, inventions, trade-marks, copyrights, royalty payments, and matters connected therewith; as may be prescribed by the Secretary of the Navy. All of the duties of this Office shall be performed under the authority of the Secretary of the Navy and its orders shall be considered as emanating from him and shall have full force and effect as such.

SEC. 2. At the head of the Office of Naval Research there shall be a Chief of Naval Research, appointed by the President, by and with the advice and consent of the Senate, for a term of not to exceed three years, from among officers not below the grade of commander on the active list of the Navy. The Chief of Naval Research shall have the same rank and shall be entitled to the same pay, allowances, and privileges of retirement as are now or may hereafter be prescribed by or in pursuance of law for chiefs of bureaus in the Navy Department.

SEC. 3. An officer on the active list of the Navy may be detailed as Assistant Chief of Naval Research, and such officer shall receive the highest pay of his grade and in case of the death, resignation, absence, or sickness of the Chief of Naval Research, shall, until otherwise directed by the President as provided in Revised Statutes, section 179 (U. S. C., title 5, sec. 6), perform the duties of such chief until his successor is appointed or such absence or sickness shall cease.

SEC. 4. The Secretary of the Navy is hereby authorized to establish a Naval

THE BILL (H. R. 1180)

SEC. 3. Contracts of the military departments for services and use of facilities for research or development may be made for a term not to exceed five years, and may be extended for an additional period not to exceed five years, subject to the availability of appropriations therefor.

SEC. 4. An contract of the military departments for research or development, or both, may provide for the acquisition or construction, by, or furnishing to, the contractor of such research, developmental, or test facilities and equipment as may be determined by the Secretary concerned to be necessary for the performance thereof. Such research, developmental, or test facilities and equipment including specialized housing therefor, may be acquired or constructed at Government expense, and may be furnished to the contractor by lease, loan, or sale at fair value, and with or without reimbursement to the Government for the use thereof: *Provided*, That nothing contained in this subsection shall be deemed to authorize new construction or improvements having general utility: *Provided further*, That nothing contained herein shall be deemed to authorize the installation or construction of facilities on property not owned by the Government which would not be readily removable or separable without unreasonable expense or unreasonable loss of value, unless adequate provision is made in the contract for (1) reimbursement to the Government of the fair value of such facilities upon the completion or termination of the contract, or within a reasonable time thereafter, or (2) an option in the Government to acquire the underlying land, or (3) such other provisions as will in the opinion of the Secretary concerned be adequate to protect the Government's interest in such facilities: *And provided further*, That all moneys arising from sales or reimbursement under this section shall be

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Research Advisory Committee, which shall consist of not exceeding fifteen persons to be appointed by the Secretary from those persons in civilian life who are preeminent in the fields of science, research, and development work. One member of such committee will be from the field of medicine. The members of such committee shall serve for such term or terms as the Secretary may specify, and shall meet at such times as may be specified by the Secretary to consult with and advise the Chief of Naval Operations and the Chief of the Office of Naval Research. Each member of such committee shall be entitled to compensation in the amount of $50 for each day or part of a day he shall be in attendance at any regularly called meeting of the committee, together with reimbursement for all travel expenses incident to such attendance: Provided, That nothing contained in sections 41, 109, and 113 of the Criminal Code (U. S. C., title 18, secs. 93, 198, and 203); in Revised Statutes, section 190 (U. S. C., title 5, sec. 99); in section 19 (e) of the Contract Settlement Act of 1944 (Public Law 395, Seventy-eighth Congress); or in any other provision of Federal law imposing restrictions, requirements, or penalties in relation to the employment of persons, the performance of services, or the payment or receipt of compensation in connection with any claim proceeding, or matter involving the United States, shall apply to such persons solely by reason of their appointment to and membership on such committee.

SEC. 5. (a) There is hereby authorized to be appropriated such amounts as may be necessary for the Office of Naval Research to carry out its functions as provided for herein, including such sums as may be required for administrative expenses, and the conduct of research and development work in

THE BILL (H. R. 1180)

covered into the Treasury as miscellaneous receipts, except to the extent otherwise authorized by law with respect to contractor-acquired property.

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SEC. 5. With the approval of the Secretary concerned, any contract of the military departments for research or development, or both, may provide that the Government will indemnify the contractor against either or both of the following, to the extent that they arise out of the direct performance of said contract and are not compensated by insurance or otherwise: (1) Liability on account of claims (including reasonable expenses of litigation or settlement of such claims) by third persons, including employees of the contractor, for death, bodily injury, or loss of or damage to property, arising as a result of a risk defined in the contract to be unusually hazardous: *Provided*, That any contract so providing shall also contain appropriate provisions for notice to the Government of suits or actions filed or claims made, against the contractor, with respect to any alleged liability for such death, bodily injury, or loss of or damage to property, and for control of or assistance in the defense of any such suit, action, or claims, by the Government, at its election; and (2) loss of or damage to property of the contractor arising as a result of a risk defined in the contract to be unusually hazardous: *And provided further*, That no payment shall be made by the Government under authority of this section unless the amount thereof shall first have been certified to be just and reasonable by the Secretary concerned or by an official of the department designated for such purpose by the Secretary. Any such payment may be made, with the approval of the Secretary concerned, out of any funds obligated for the performance of such contract or out of

EXISTING COMPARABLE LAW

Government facilities and under contracts with private individuals, corporations, and educational or scientific institutions. Sufficient information relative to estimates of appropriations for research by the several bureaus and offices shall be furnished to the Chief of the Office of Naval Research to assist him in coordinating the Navy research program and the carrying out of such other duties as outlined in section 1.

(b) Any funds appropriated to enable the Office of Naval Research to carry out its functions as provided for herein shall, if obligated during the fiscal year for which appropriated, remain available for expenditure for four years following the expiration of the fiscal year for which appropriated. After such a four-year period, the unexpended balances of appropriations shall be carried to the surplus fund and covered into the Treasury.

SEC. 6. Within the limits of available appropriations, the Secretary of the Navy, and, by direction of the Secretary, the Chief of the Office of Naval Research and the chiefs of all bureaus of the Navy Department may enter into contracts, or amendments or modifications of contracts, for services and materials necessary for the making and securing of reports, tests, models, apparatus, and for the conducting of research, without performance or other bonds, and without regard to section 3709 of the Revised Statutes (U. S. C., title 41, sec. 5) section 3718 of the Revised Statutes (U. S. C., title 34, sec. 561), section 3719 of the Revised Statutes (U. S. C., title 34, sec. 562), section 3720 of the Revised Statutes (U. S. C., title 34, sec. 563), section 3722 of the Revised Statutes (U. S. C., title 34, sec. 572), and may make advance, progress, and other payments with respect to such contracts without regard to the provisions of section 3648 of the Revised Statutes (U. S. C., title

THE BILL (H. R. 1180)

funds available for research and development work and not otherwise obligated; or out of any funds appropriated by the Congress for the making of such payments.

SEC. 6. Each of the Secretaries of the military department is authorized to prescribe, with the approval of the Secretary of Defense and of the Comptroller General of the United States, regulations for his department stating the extent to which vouchers for funds expended under any contract for research or development, or both, shall be subject to itemization, substantiation, or certification prior to payment, without regard to the limitations of other laws relating to the expenditure of public funds and accounting therefor.

SEC. 7. Each of the Secretaries of the military departments is authorized to arrange for the publication of scientific and technical information resulting from

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the research and development activities of his department, so as to further the full dissemination of information of scientific value consistent with the national interest without regard to the provisions of section 87 of the Act of January 12, 1895 (28 Stat. 662), as amended, or of section 2 of the Act of June 30, 1906 (34 Stat. 762), as amended.

SEC. 8. Each of the Secretaries of the military departments is authorized to delegate any authority provided by this Act to the Under Secretary or any Assistant Secretary of his department and, except the authority under the second proviso in section 4 hereof, the said Secretaries may delegate any authority provided by this Act to the chiefs of the technical services, bureaus, or offices and to one assistant to each such chief. The power to negotiate, execute, and administer contracts for research or development, or both,

EXISTING COMPARABLE LAW

31, sec. 529): Provided, That nothing herein shall be construed to authorize the use of the cost-plus-a-percentage-of-cost system of contracting.

SEC. 7. The Secretary of the Navy is authorized to transfer to the Office of Naval Research, as in his judgment may be necessary and appropriate, such research and development functions as are now assigned to the various bureaus and other agencies and offices of the Navy Department, together with any or all personnel, buildings, facilities, and other property used in the administration thereof, including without limitation the Special Devices Division and the Naval Research Laboratory.

NATIONAL SECURITY ACT OF 1947, AS AMENDED BY THE NATIONAL SECURITY ACT AMENDMENTS OF 1949.

(Research and Development Board)

"SEC. 214. (a) There is hereby established in the Department of Defense a Research and Development Board (hereinafter in this section referred to as the 'Board'). The Board shall be composed of a Chairman, who shall be the head thereof and who shall, subject to the authority of the Secretary of Defense and in respect to such matters authorized by him, have the power of decision on matters falling within the jurisdiction of the Board, and two representatives from each of the Departments of the Army, Navy, and Air Force, to be designated by the Secretaries of their respective Departments. The Chairman shall be appointed from civilian life by the President, by and with the advice and consent of the Senate, and shall receive compensation at the rate of $14,000 a year. The purpose of the Board shall be to advise the Secretary of Defense as to the status of scientific research relative to the national security, and to assist him in assuring adequate provision for research and development on scientific problems relating

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may be further delegated, subject to the provisions of any other applicable law.

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EXISTING COMPARABLE LAW

to the national security.

"(b) Subject to the authority and direction of the Secretary of Defense, the Board shall perform the following duties and such other duties as the Secretary of Defense may prescribe:

"(1) preparation of a complete and integrated program of research and development for military purposes;

"(2) advising with regard to trends in scientific research relating to national security and the measures necessary to assure continued and increasing progress;

"(3) coordination of research and development among the military departments, and allocation among them of responsibilities for specific programs;

"(4) formulation of policy for the Department of Defense in connection with research and development matters involving agencies outside the Department of Defense; and

"(5) consideration of the interaction of research and development and strategy, and advising the Joint Chiefs of Staff in connection therewith.

"(c) When the Chairman of the Board first appointed has taken office, the Joint Research and Development Board shall cease to exist and all its records and personnel shall be transferred to the Research and Development Board.

"(d) The Secretary of Defense shall provide the Board with such personnel and facilities as the Secretary may determine to be required by the Board for the performance of its functions."

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1.14a(2) SENATE COMMITTEE ON ARMED SERVICES

S. REP. No. 936, 82nd Cong., 1st Sess. (1951)

FACILITATING THE PERFORMANCE OF RESEARCH AND DEVELOPMENT WORK BY AND ON BEHALF OF THE DEPARTMENTS OF THE ARMY, THE NAVY, AND THE AIR FORCE

OCTOBER 11 (legislative day, OCTOBER 1), 1951.—Ordered to be printed

MR. STENNIS, from the Committee on Armed Services, submitted the following

REPORT

[To accompany H.R. 1180]

The Committee on Armed Services, to whom was referred the bill H.R. 1180, to facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes, having considered the same, report favorably thereon, without amendments, and recommend that the bill do pass.

PURPOSE OF THE BILL

The proposed legislation would provide the three military departments with certain administrative authority required to carry out their research and development programs.

EXPLANATION OF THE BILL

Background of the pending bill

The bill is substantially the same as S. 1560, Eightieth Congress, which was passed by the Senate on June 1, 1948, but concerning which no action was taken by the House of Representatives. The pending bill introduces no change in policy or procedure not contemplated in S. 1560, Eightieth Congress.

General authority for research and development

The Army and Air Force Organization Act of 1949 contains general authority for research and development programs to be carried out by the Departments of the Army and Air Force. The

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Department of the Navy carries out its research and development program under the authority of the act of August 1, 1946 (60 Stat. 779). The National Security Act of 1947, as amended by the National Security Act Amendments of 1949, makes provision for the authority of the Secretary of Defense and the Research and Development Board with respect to research and development programs within the Department of Defense.

H.R. 1180 does not disturb these general authorities and relationships but is intended to provide the three military departments with certain administrative powers which are essential for them to implement the general authority which they now have to conduct such programs.

Major provisions of the bill

The more important administrative powers which the bill provides are listed below:

(1) The appointment of research advisory committees;

(2) The employment of alien scientists and technicians;

(3) The periodic renewal of research contracts;

(4) The furnishing of Government facilities;

(5) The indemnification against damage loss, where the contractor is unable to procure insurance coverage;

(6) A simplified voucher procedure, the requirements of which can be met by colleges, universities, institutes, and other contractors; and

(7) The publication and dissemination of scientific and technical information.

A more detailed discussion of each of the sections of the bill is contained in the section-by-section analysis which follows.

SECTION-BY-SECTION ANALYSIS

Section 1. Establishment of research and development advisory committees

This section provides for the establishment of research and advisory committees and panels and for the employment of such part-time advisory personnel as the Secretaries deem necessary in carrying out research and development activities.

Wartime experience demonstrated that such committees or panels and part-time consultants were of invaluable assistance in the conduct of research and development programs. Such groups make it possible for the country to avail itself of the best scientific minds to deal with both the planning and the execution of projects of the type for which professional personnel of the armed services are not particularly equipped.

The bill provides that members of such committees and panels and advisory personnel may serve either with or without compensation and shall be exempt from the conflict of interest sections of title 18 of the United States Code.

The authority to pay compensation at the rate of not to exceed $50 per day of service is comparable to that contained in the 1949 amendments to the National Security Act. It should be pointed out that this language does not constitute a new or separate authority for the employment of consultants. The committee is mindful of

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the fact that substantial numbers of consultants are already employed by the Federal Government based upon authorizations contained in various appropriations acts. One of the beneficial results of the bill S. 913 (Mr. McClellan), which would establish a Joint Budget Committee to service and work on the Federal budget, would be a scrutiny of the justifications for selection and employment of this category of personnel.

Section 2. Employment of noncitizens

This section authorizes the employment of scientific and technical persons, whether or not they are citizens of the United States. Many of the experts in these fields are noncitizens and this authority will permit the employment of such persons under the provisions of Public Law 600, Seventy-ninth Congress.

Section 3. Contracts

This section provides for long-term contracts. Research and development programs must be planned far in advance. The individual projects which contribute to the over-all programs are unpredictable both as to results and as to the length of time required for completion. Continuing funds as authorized in the Army and Air Force Authorization Act of 1949, together with a 5-year contract term plus provision for additional 5-year contract renewals, will provide the necessary continuity. Under the proposed system the Bureau of the Budget and the Congress would not lose control over appropriated funds. In the case of each activity Congress would be presented annually with a single figure representing the "bank balance" of that activity.

A large percentage of research and development activities are conducted by contract with civilian institutions. The inability of the military services to conform to established business practices in making long-term contracts seriously impairs this relationship. A prospective contractor hesitates to commit a highly trained staff, recruited with difficulty, for fear of termination of the work when the contract is on a short-term basis. Accelerated progress in critical fields may thus be retarded until a subsequent appropriation to cover an amendment or a new contract can be justified.

Authority to place long-term contracts is considered essential to meet the foregoing requirements.

Section 4. Furnishing of certain essential facilities to contractors

This section provides for the furnishing of necessary research, developmental or test facilities to contractors, subject to adequate protection of the Government's interests therein. Under the provisions of this section, the military departments may utilize research and development funds for the furnishing or construction of equipment or facilities for the use of contractors where appropriate. Wartime experience indicates that situations arise in which contractors require special facilities for the performance of their contracts. Since in many cases these facilities would be of no use to them apart from the performance of such contracts, they are unable to provide the facilities at their own expense. On the other hand, to permit contract prices to include sufficient amounts to cover the cost of such facilities, would obviously be unfair to the Government in that the Government would, in effect, be not only [p. 3] buying the facilities, but would then leave them in the possession of the contractor. The solution proposed herein is to authorize the Government to provide such facilities, at the same time protecting its interest therein.

Section 5. Authority to indemnify contractors against liability and loss arising from injury or damage

This section provides authority for the military departments to agree to indemnify contractors against liability and loss resulting from injury to persons or damage to property arising out of the direct performance of a research and development contract, to the extent that such losses are not compensated by insurance or otherwise. In many cases, contractors are reluctant to undertake a research or development contract involving extremely hazardous new developments without securing adequate protection in the event of liability resulting from claims made as a result of damage from those experiments. No provision can be made for such protection by including a reserve in the contract price, and the cost of insurance, if at all obtainable, would be prohibitive. The solution is for the Government to agree to indemnify such a contractor, subject to the safeguards provided in this section.

Section 6. Simplified vouchering procedures

This section provides authority for the Secretaries of the military departments, with the approval of the Secretary of Defense and the Comptroller General to promulgate regulations stating the extent to which vouchers for funds expended under any research and development contract shall require itemization or substantiation prior to payment. Universities and nonprofit institutions, in which much research is conducted, as well as some commercial organizations, are not equipped to handle the detailed vouchering procedures and auditing technicalities required. Difficulty is experienced in negotiating contracts with these institutions for that reason. Relaxed procedures were applied to contracts let by the Office of Scientific Research and Development during the war and proved highly satisfactory. The requirement of approval by the Secretary of Defense and the Comptroller General is an important safeguard on the extent to which this authority will be used.

Section 7. Authorization for scientific and technical publications

This section 7 provides authority for the prompt publication of scientific and technical information developed by the departments, which will be extremely useful in disseminating such information. It frequently will be advantageous for the departments to avail themselves of specialized means of distribution of such information, such as the use of the services and mailing lists of appropriate learned societies. The current situation of inflation, increased costs, and the consequent shrinkage in media of publication of scientific work, plus increased scientific activity, has resulted in considerable difficulty in the publication of the findings of scientific work. Scientific progress is directly related to the prompt dissemination of technical data to others who are engaged in similar work. It is to the interest of the military service to assist in such dissemination of information, subject to security controls. This section provides the means to that end, and also excludes such material from the [p. 4] provisions of law which generally require that all printing for Government agencies shall be done at the Government Printing Office.

Section 8. Delegation of authority

This section authorizes the Secretaries of the military departments to delegate any authority provided by this act to the Under or Assistant Secretaries of the Departments, the chiefs of the technical services, bureaus or offices, and to one assistant of each such chief. Such delegation of authority is normal and is considered essential in order to achieve the necessary facility and flexibility of operation.

CONCLUSION

There can be no question that the future security of our Nation depends largely upon our military research and development programs. The purpose of the proposed bill is to provide the armed services with adequate means for properly discharging their research and development responsibilities.

As previously noted, it is impossible to predict unforeseen hazards which may create liabilities under the indemnity provisions contained in section 5 of the proposed bill. It is anticipated that the departments will continue their current policy of having contractors insure employees against hazards in doing research contract work where the premiums on such insurance are not prohibitively costly. It is recognized that some of the undertakings in the research and development contracts are so hazardous that they cannot be insured in any amount. If such contracts are to be undertaken there is no other solution than that of having the Government agree to indemnify the contractor if liability should be sustained by him. Except for this possibility, the proposed legislation will result in no increased cost to the Government.

RECOMMENDATION OF DEPARTMENT OF DEFENSE

The proposed legislation is a part of the Department of Defense legislative program for 1951 and it has been approved by the Bureau of the Budget. The Department of Defense recommends that it be enacted by the Congress as is evidencd by the report of the Secretary of Defense which is hereto attached and made a part of this report.

ASSISTANT SECRETARY OF DEFENSE,
Washington 25, D. C. January 5, 1951.

Hon. RICHARD B. RUSSELL,
Chairman, Committee on Armed Services,
United States Senate.

DEAR MR. CHAIRMAN: There is forwarded herewith a draft of legislation to facilitate the performance of research and development work by and on behalf of the Army, the Navy, and the Air Force, and for other purposes, together with a sectional analysis thereof.

This proposed legislation is a part of the Department of Defense legislative program for 1951 and it has been approved by the Bureau of the Budget. The Department of Defense recommends that it be enacted by the Congress.

Purpose of the legislation.—The purpose of this legislation is to provide the military departments with administrative authority required to carry out research and development programs. General authority for research and development programs of the Departments of the Army and Air Force is provided by the Army and Air Force Authorization Act of 1949, while the Department of

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the Navy carries out its research and development program under the authority of the act of August 1, 1946 (60 Stat. 779). The National Security Act of 1947, as amended, provides for the authority of the Secretary of Defense and the Research and Development Board with respect to all research and development programs of the Department of Defense. This legislation is not designed to affect such general authorities and relationships but merely to provide the military departments with administrative powers which are essential in order to effectively implement the general authority to conduct such programs.

These essential powers are:

(1) The appointment of research advisory committees;

(2) The employment of alien scientists and technicians;

(3) The periodic renewal of research contracts;

(4) The furnishing of Government facilities;

(5) The indemnification against damage loss, where the contractor is unable to procure insurance coverage;

(6) A simplified voucher procedure, the requirements of which can be met by colleges, universities, institutes, and other contractors; and

(7) The publication and dissemination of scientific and technical information.

Legislative references.—Legislation similar to this proposal was introduced in the Eightieth Congress (S. 1560). S. 1560 was passed by the Senate (S. Rept. No. 1397), but was not reported out of the House committee before adjournment.

The Army and Air Force Authorization Act of 1949 (Public Law 604, 81st Cong.) which was approved on July 10, 1950, authorized the Departments of the Army and Air Force to conduct, engage, and participate in research and development programs and to procure or contract for facilities, equipment, services, and supplies to effectuate such programs. That act also provided for the continued availability of appropriations to the Departments of the Army, Navy, and Air Force for research and development.

Legislation identical with this proposal except for technical changes and the omission of authority for the continued availability of appropriations for research and development in the enclosed draft, was included in the Department of Defense legislative program for consideration by the Eighty-first Congress, second session, approved by the Bureau of the Budget, and introduced in the Congress (S. 3521 and H.R. 8352). No further action was taken by the Eighty-first Congress with respect to S. 3521 and H.R. 8352.

Cost and budget data.—Enactment of the proposed legislation should result in no additional expenditure of public funds, except to the extent that unforeseen hazards may create liabilities under the indemnity provisions of the proposed legislation. It is impossible to foresee the extent of claims under those provisions.

Department of Defense action agency.—The Department of the Army has been designated as the representative of the Department of Defense for this legislation.

Sincerely yours,

MARX LEVA,

The following statutes set forth existing provisions of law which are related to the authority recommended in the proposed legislation and are included in this report as a matter of convenience:

ARMY AND AIR FORCCE AUTHORIZATION ACT OF 1949—RESEARCH AND DEVELOPMENT AUTHORIZATION

(Army Authority)

SEC. 104. The Secretary of the Army is hereby authorized to conduct engage, and participate in research and development programs related to activities of the Army of the United States and to procure, or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs.

(Air Force Authority)

SEC. 205. The Secretary of the Air Force is hereby authorized to conduct, engage, and participate in research and development programs related to activities of the Air Force of the United States and to procure, or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs.

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(Army, Navy, and Air Force Appropriation Authority)

SEC. 303. (a) There are hereby authorized to be appropriated, out of any moneys in the Treasury of the United States not otherwise appropriated, such sums as may be necessary to carry out the purposes of this Act.

(b) Moneys appropriated to the Department of the Army, Navy, or Air Force for procurement of technical military equipment and supplies, the construction of public works, and for research and development, including moneys appropriated to the Department of the Navy for the procurement, construction, and research and development of guided missiles, which are hereby authorized for the Department of the Navy, shall remain available until expended unless otherwise provided in the appropriation Act concerned.

ACT OF AUGUST 1, 1946 (60 STAT. 779)

(Office of Naval Research)

* * * That there is hereby created and established in the Office of the Secretary of the Navy an Office of Naval Research, which shall be charged with such duties relating to (1) the encouragement, promotion, planning, initiation, and coordination, of naval research; (2) the conduct of naval research in augmentation of and in conjunction with the research and development conducted by the respective bureaus and other agencies and offices of the Navy Department; and (3) the supervision, administration, and control of activities within or on behalf of the Department of the Navy relating to patents, inventions, trademarks, copyrights, royalty payments, and matters connected therewith; as may be prescribed by the Secretary of the Navy. All of the duties of this Office shall be performed under the authority of the Secretary of the Navy and its orders shall be considered as emanating from him and shall have full force and effect as such.

SEC. 2. At the head of the Office of Naval Research there shall be a Chief of Naval Research, appointed by the President, by and with the advice and consent of the Senate, for a term of not to exceed 3 years, from among officers not below the grade of commander on the active list of the Navy. The

Chief of Naval Research shall have the same rank and shall be entitled to the same pay, allowances, and privileges of retirement as are now or may hereafter be prescribed by or in pursuance of law for chiefs of bureaus in the Navy Department.

SEC. 3. An officer on the active list of the Navy may be detailed as Assistant Chief of Naval Research, and such officer shall receive the highest pay of his grade and in case of the death, resignation, absence, or sickness of the Chief of Naval Research, shall until otherwise directed by the President as provided in Revised Statutes, section 179 (U.S.C., title 5, sec. 6), perform the duties of such chief until his successor is appointed or such absence or sickness shall cease.

SEC. 4. The Secretary of the Navy is hereby authorized to establish a Naval Research Advisory Committee, which shall consist of not exceeding fifteen persons to be appointed by the Secretary from those persons in civilian life who are preeminent in the fields of science, research, and development work. One member of such committee will be from the field of medicine. The members of such committee shall serve for such term or terms as the Secretary may specify, and shall meet at such times as may be specified by the Secretary to consult with and advise the Chief of Naval Operations and the Chief of the Office of Naval Research. Each member of such committee shall be entitled to compensation in the amount of $50 for each day or part of a day he shall be in attendance at any regularly called meeting of the committee, together with reimbursement for all travel expenses incident to such attendance; *Provided*, That nothing contained in sections 41, 109, and 113 of the Criminal Code (U. S. C., title 18, secs. 93, 198, and 203); in Revised Statutes, section 190 (U. S. C., title 5, sec. 99); in section 19 (e) of the Contract Settlement Act of 1944 (Public Law 395, Seventy-eighth Congress); or in any other provision of Federal law imposing restrictions, requirements, or penalties in relation to the employment of persons, the performance of services, or the payment or receipt of compensation in connection with any claim proceeding, or matter involving the United States, shall apply to such persons solely by reason of their appointment to and membership on such committee.

SEC. 5. (a) There is hereby authorized to be appropriated such amounts as may be necessary for the Office of Naval Research to carry out its functions as provided for herein, including such sums as may be required for administrative [p. 7] expenses, and the conduct of research and development work in Government facilities and under contracts with private individuals, corporations, and educational or scientific institutions. Sufficient information relative to estimates of appropriations for research by the several bureaus and offices shall be furnished to the Chief of the Office of Naval Research to assist him in coordinating the Navy research program and the carrying out of such other duties as outlined in section 1.

(b) Any funds appropriated to enable the Office of Naval Research to carry out its functions as provided for herein shall, if obligated during the fiscal year for which appropriated, remain available for expenditure for 4 years following the expiration of the fiscal year for which appropriated. After such a 4-year period, the unexpended balances of appropriations shall be carried to the surplus fund and covered into the Treasury.

SEC. 6. Within the limits of available appropriations, the Secretary of the Navy, and, by direction of the Secretary, the Chief of the Office of Naval

Research and the chiefs of all bureaus of the Navy Department may enter into contracts, or amendments or modifications of contracts, for services and materials necessary for the making and securing of reports, tests, models, apparatus, and for the conducting of research, without performance or other bonds, and without regard to section 3709 of the Revised Statutes (U. S. C., title 41, sec. 5), section 3718 of the Revised Statutes (U. S. C., title 34, sec. 561), section 3719 of the Revised Statutes (U. S. C., title 34, sec. 562), section 3720 of the Revised Statutes (U. S. C., title 34, sec. 563), section 3722 of the Revised Statues (U. S. C., title 34, sec. 572), and may make advance, progress, and other payments with respect to such contracts without regard to the provisions of section 3648 of the Revised Statutes (U. S. C., title 31, sec. 529): *Provided*, That nothing herein shall be construed to authorize the use of the cost-plus-a-percentage-of-cost system of contracting.

SEC. 7. The Secretary of the Navy is authorized to transfer to the Office of Naval Research, as in his judgment may be necessary and appropriate, such research and development functions as are now assigned to the various bureaus and other agencies and offices of the Navy Department, together with any or all personnel, buildings, facilities, and other property used in the administration thereof, including without limitation the Special Devices Division and the Naval Research Laboratory.

NATIONAL SECURITY ACT OF 1947, AS AMENDED BY THE NATIONAL SECURITY ACT AMENDMENTS OF 1949

(Research and Development Board)

"SEC. 214. (a) There is hereby established in the Department of Defense a Research and Development Board (hereinafter in this section referred to as the 'Board'). The Board shall be composed of a Chairman, who shall be the head thereof and who shall, subject to the authority of the Secretary of Defense and in respect to such matters authorized by him, have the power of decision on matters falling within the jurisdiction of the Board, and two representatives from each of the Departments of the Army, Navy, and Air Force, to be designated by the Secretaries of their respective Departments. The Chairman shall be appointed from civilian life by the President, by and with the advice and consent of the Senate, and shall receive compensation at the rate of $14,000 a year. The purpose of the Board shall be to advise the Secretary of Defense as to the status of scientific research relative to the national security, and to assist him in assuring adequate provision for research and development on scientific problems relating to the national security.

"(b) Subject to the authority and direction of the Secretary of Defense, the Board shall perform the following duties and such other duties as the Secretary of Defense may prescribe:

"(1) preparation of a complete and integrated program of research and development for military purposes;

"(2) advising with regard to trends in scientific research relating to national security and the measures necessary to assure continued and increasing progress;

"(3) coordination of research and development among the military departments, and allocation among them of responsibilities for specfic programs;

"(4) formulation of policy for the Department of Defense in connection with research and development matters involving agencies outside the Department of Defense; and

"(5) consideration of the interaction of research and development and strategy, and advising the Joint Chiefs of Staff in connection therewith.

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"(c) When the Chairman of the Board first appointed has taken office, the Joint Research and Development Board shall cease to exist and all its records and personnel shall be transferred to the Research and Development Board.

"(d) The Secretary of Defense shall provide the Board with such personnel and facilities as the Secretary may determine to be required by the Board for the performance of its functions."

SEC. 303. (a) The Secretary of Defense, the Chairman of National Security Resources Board, the Director of Central Intelligence, and the National Security Council, acting through its Executive Secretary, are authorized to appoint such advisory committees and to employ, consistent with other provisions of this Act, such part-time advisory personnel as they may deem necessary in carrying out their respective functions and the functions of agencies under their control. Persons holding other offices or positions under the United States for which they receive compensation, while serving as members of such committees, shall receive no additional compensation for such service. Other members of such committees and other part-time advisory personnel so employed may serve without compensation or may receive compensation at a rate not to exceed $50 for each day of service, as determined by the appointing authority.

(b) Service of an individual as a member of any such advisory committee, or in any other part-time capacity for a department or agency hereunder, shall not be considered as service bringing such individual within the provisions of sections 109 or 113 of the Criminal Code (U. S. C., 1940 edition, title 18, secs. 198 and 203) or section 19 (e) of the Contract Settlement Act of 1944, unless the act of such individual, which by such section is made unlawful when performed by an individual referred to in such section, is with respect to any particular matter which directly involves a department or agency which such person is advising or in which such department or agency is directly interested.

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1.14a(3) CONGRESSIONAL RECORD

1.14a (3) (a) VOL. 97 (1951), Aug. 2: Passed House, pp. 9431–9433

ARMED SERVICES RESEARCH AND DEVELOPMENT WORK

Mr. SABATH. Mr. Speaker, I call up House Resolution 358 and ask for its immediate consideration.

The Clerk read as follows:

Resolved, That immediately upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H. R. 1180) to facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes. That after general debate, which shall be confined to the bill and continue not to exceed 1 hour, to be equally divided and controlled by the chairman and ranking minority member of the Committee on Armed Services, the bill shall be be read for amendment under the 5-minute rule. At the conclusion of the consideration of the bill for amendment, the Committee shall rise and report the bill to the House with such amendments as may have been adopted and the previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit.

Mr. SABATH. Mr. Speaker, House Resolution 358 makes in order the bill (H. R. 1180) to facilitate the performance of research and development work by and on behalf of the Department of the Army, the Navy, and the Air Force.

The bill was unanimously reported from the great Committee on Armed Services, and its very able and efficient chairman the gentleman from Georgia [Mr. VINSON] so thoroughly convinced the membership of my Committee on Rules that it, too, voted to report this rule unanimously. And while there is 1 hour of debate allowed on this rule, I feel certain it will not be utilized. As for myself, realizing that Members have so many important matters to attend to, I shall not detain them.

Mr. Speaker, I yield 30 minutes to the gentleman from Ohio [Mr. BROWN], a member of the Committee on Rules, and reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentleman from Nebraska [Mr. MILLER].

Mr. MILLER of Nebraska. Mr. Speaker, the bill we have before us now is important. I am sorry it is called up at a time when we have so few Members present, because it is of sufficient importance that we ought to have a thorough look at its contents. I am going to support the bill. I do want to point out that the bill does set up and let each one of the Secretaries in the departments have their own advisory committees as far as scientific developments are concerned. Each Secretary shall appoint an advisory committee. There is no limit to the number of committees; there is no limit to the number of $50-a-day men they may put on the payroll. I was under the impression that we had unification of the armed services. I have been under that impression for some time.

Mr. SABATH. Mr. Speaker, will the gentleman yield?

Mr. MILLER of Nebraska. I yield to the gentleman from Illinois.

Mr. SABATH. The members of these advisory committees will not be on the payroll. They will be allowed so much per day when they are called upon to perform duties.

Mr. MILLER of Nebraska. Yes; let me quote from the bill:

> Each of the Secretaries of the military departments is hereby authorized to establish such advisory committees or panels as may be necessary for the conduct of the research and development activities of his department.

And on page 2 it says that they may be paid up to $50 for each day of service, as determined by the appointing authority.

I submit to you if we are going to have unification we do not need three separate advisory committees, one for each Secretary, with a large group of people, we do not know how many there will be, at $50 a day advising upon scientific matters.

I am willing to support this bill, but I want to point these things out. I think it is bad procedure. If we are going to have unification of the armed services we ought to say that there shall be one advisory committee on scientific research. Of course, no advance is ever made in the country unless we do have research and examination of things. After all, research is nothing more than inquiring and asking questions of the unknown and seeking the answers. But here we are making it possible for the three Secretaries of the Armed Forces to use specialists and all working along the same lines without coordination.

In my own memory I do not know of any great scientific advance that has been made by the Government, certainly not in medicine and in any scientific field in which I am acquainted. The Government itself has never made one contribution to society in that respect and I doubt very much if they have in the military field. Your great advance in medicine comes in scientific performance when freemen with free minds can go out and explore into the unknown, find and come up with the answer. That is where the progress has been made. When freemen become fettered by Government regulations, as I am afraid they will under this bill, no progress is made. I think you have to have some scientific men, but you have to take them from private life, not from Government. Of course, these men who are on the Government payroll do not get extra pay. However, I am sure that advance in science, and scientific attainment, under this type of bill will come from industry, not by Government effort. It has always been true that every time the Government lays its cold and clammy hand on scientific development then progress stops. [p. 9431] The great advance in the past comes with the minimum of interference by the Government. The scientific mind does not perform when restricted by red tape.

I realize there are other things in the bill besides the matter of the appointment or the establishment of advisory committees, and I have no objection to them. I do hope that when the bill is adopted perhaps these three Secretaries can get together and will not have three advisory committees and a lot of people on the payroll at $50 a day doing the same work. Do we have unification of the Armed Forces when you permit the three Secretaries, and probably we will have a fourth in the Marine Corps set-up, having advisory committees doing the same work? There ought to be unity and a complete exchange of ideas. Right now in Washington—England, Canada, France and the United States are trying to standardize their small arms. That is all to the good.

I would like this bill better if all the Secretaries had their scientific committees under one umbrella and their work coordinated—it would save the taxpayers money.

Mr. BROWN of Ohio. Mr. Speaker, I yield 1 minute to the gentleman from Illinois [Mr. ARENDS].

Mr. ARENDS. Mr. Speaker, I take this time for the purpose of inquiring of the majority leader if he can at this time inform the House as to the program for next week.

Mr. McCORMACK. I will be glad to.

On Monday we will take up the Consent Calendar. There will also be two suspensions. One is H. R. 4288, interstate compacts, Texas and Louisiana, and the other is H. R. 3830, geomagnetic station construction. I understand that that bill would have been considered by unanimous consent except for the fact that it slightly exceeded the amount that the screening committee felt should not be passed by unanimous consent.

On Tuesday there will be the call of the Private Calendar.

Wednesday, and for the remainder of the week, we will take up the Department of Defense appropriation bill, 1952.

There are primaries in Mississippi and Virginia on Tuesday, and of course, we have an understanding that on those days no roll calls will be had. The only business on that day will be the call of the Private Calendar.

Conference reports, of course, may be brought up at any time, but none will be brought up on Monday or Tuesday. I make that statement so that the Members of the House can govern themselves accordingly.

Any further program or change in program, of course, for next week, will be announced as soon as possible later on.

Mr. ARENDS. Is it the hope to finish the Department of Defense appropriation bill next week?

Mr. McCORMACK. Oh, yes, because the week after next we expect to have the ECA authorization bill up. With the Department of Defense appropriation bill and the ECA appropriation bill, which ought to follow quickly, out of the way, daylight can be seen for some 3-day recesses. I do not know how many, and I cannot make any promises, but I have been driving for it since last January.

Mr. ARENDS. That is the best ray of sunshine I have had for a long time, and I think that goes for all the Members.

Mr. McCORMACK. I thank the gentleman.

Mr. SABATH. Mr. Speaker, I move the previous question on the resolution.

The previous question was ordered.

The resolution was agreed to.

Mr. BROOKS. Mr. Speaker, there is no opposition to this bill, so I ask unanimous consent that we waive the terms of the resolution requiring us to go into the Committee of the Whole House on the State of the Union and that in lieu thereof the bill be printed at this point, and be considered in the House under the 5-minute rule.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mr. KELLEY of Pennsylvania). Is there objection to the request of the gentleman from Louisiana?

There was no objection.

The bill is as follows:

Be it enacted, etc., That each of the Secretaries of the military departments is hereby authorized to establish such advisory committees or panels as may be necessary for the conduct of the research and development activities of his department, and to employ such part-time advisory personnel as they may deem necessary in carrying out such activities. Persons holding other offices or positions under the United States for which they receive compensation, while serving as members of such committees, shall receive no additional compensation for such service. Other members of such committees and other part-time advisory personnel so employed may serve without compensation or may receive compensation at a rate not to exceed $50 for each day of service, as determined by the appointing authority.

Service of an individual as a member of any such advisory committee, or in any other part-time capacity for a department hereunder, shall not be considered as service bringing such individual within the provisions of sections 281, 283, or 284 of title 18, United States Code, unless the act of such individual, which by such section is made unlawful when performed by an individual referred to in such section, is with respect to any particular matter which directly involves a department which such person is advising or in which such department is directly interested. The provisions of the act of July 12, 1870 (Revised Statutes, 3679), as amended, shall not apply to the acceptance of voluntary service of any member of any committee or panel authorized by this section.

SEC. 2. No provision of law prohibiting employment of or payment of compensation or expenses to any person not a citizen of the United States shall apply to any expert, scientific, technical, or professional person whose appointment or employment in connection with the research and development activities of the military departments is determined by the Secretary concerned to be necessary.

SEC. 3. Contracts of the military departments for services and use of facilities for research or development may be made for a term, not to exceed 5 years, and may be extended for an additional period not to exceed 5 years, subject to the availability of appropriations therefor.

SEC. 4. Any contract to the military departments for research or development, or both, may provide for the acquisition or construction by, or furnishing to, the contractor of such research, developmental, or test facilities and equipment as may be determined by the Secretary concerned to be necessary for the performance thereof. Such research, developmental, or test facilities and equipment, including specialized housing therefor, may be acquired or constructed at Government expense, and may be furnished to the contractor by lease, loan, or sale at fair value, and with or without reimbursement to the Government for the use thereof: *Provided*, That nothing contained in this subsection shall be deemed to authorize new construction or improvements having general utility: *Provided* further, That nothing contained herein shall be deemed to authorize the installation or construction of facilities on property not owned by the Government which would not be readily removable or separable without unreasonable expense or unreasonable loss of value, unless adequate provision is made in the contract for (1) reimbursement to the Government of the fair value of such facilities upon the completion or termination of the contract, or within a reasonable time thereafter, or (2) an option in the Government to acquire the underlying land, or (3) such other provisions as will in the opinion of the Secretary concerned be adequate to protect the Government's interest in such facilities: *And provided further*, That all moneys arising from sales or reimbursement under this section shall be covered into the Treasury as miscellaneous receipts, except to the extent otherwise authorized by law with respect to contractor-acquired property.

SEC. 5. With the approval of the Secretary concerned, any contract of the military departments for research or development, or both, may provide that the Government will indemnify the contractor against either or both of the following to the extent that they arise out of the direct performance of said contract and are not compensated by insurance or otherwise: (1) Liability on account of claims (including reasonable expenses of litigation or settlement of such claims) by third persons, including employees of the contractor, for death, bodily injury, or loss of or damage to property, arising as a result of a risk defined in the contract to be unusually hazardous: *Provided*, That any contract so providing shall also contain appropriate provisions for notice to the Government of suits or actions filed or claims made, against the contractor, with respect to any alleged liability for such death, bodily injury, or loss of or damage to property, and for control of or assistance in the defense of any such suit, action, or claims, by the Government, at its election; and (2) loss of or damage to property of the contractor arising as a result of a risk defined in the contract to be unusually hazardous; *And provided further*, That no payment shall be made by the Government under authority of this section unless the amount thereof shall first have been certified to be just and reasonable by the Secretary concerned or by an official of the department designated for such purpose by the Secretary. Any such payment may be made, with the approval of the Secretary concerned, out of any funds, obligated for the performance of such contract or out of funds available for research and development work and not otherwise obligated: or out of any funds appropriated by the Congress for the making of such payments.

SEC. 6. Each of the Secretaries of the military department is authorized to prescribe, with the approval of the Secretary of Defense and of the Comptroller General of the United States, regulations for his department stating the extent to which vouchers for funds expended under any contract for research or development, or both, shall be subject to itemization, substantiation, or certification prior to payment, without regard to the limitations of other laws relating to the expenditure of public funds and accounting therefor.

[p. 9432]

SEC. 7. Each of the Secretaries of the military departments is authorized to arrange for the publication of scientific and technical information resulting from the research and development activities of his department, so as to further the full dissemination of information of scientific value consistent with the national interest without regard to the provisions of section 87 of the act of January 12, 1895 (28 Stat. 662), as amended, or of section 2 of the act of June 30, 1906 (34 Stat. 762), as amended.

SEC. 8. Each of the Secretaries of the military departments is authorized to delegate any authority provided by this act to the Under Secretary or any Assistant Secretary of his department and, except the authority under the second proviso in section 4 hereof, the said Secretaries may delegate any authority provided by this act to the chiefs of the technical services, bureaus, or offices and to one assistant to each such chief. The power to negotiate, execute, and administer contracts for research or development, or both, may be further delegated, subject to the provisions of any other applicable law.

Mr. HEBERT. Mr. Speaker, I move to strike out the last word.

Mr. Speaker, this bill is designed to coordinate and unify the efforts of the Department of Defense in the field of research and development. It does four particular and important things: First of all, it gives to the several Secretaries of the Department of Defense the Power and the legal right to employ any individual skilled in the particular field of science in which there is a desired development.

In answer to the distinguished gentleman from Nebraska, this bill accomplishes exactly and definitely what he obviously misunderstands in his reading of it. It means that the greatest scientists in any field, without limitation, can be employed as advisers by the Department of Defense in the development of that specific science. I think that is what the gentleman objected to.

Mr. MILLER of Nebraska. No, I am not objecting to that at all. I think that is a very fine part of the bill. The gentleman said in his opening statement that it was designed to unify the departments. I claim that when you have three Secretaries, each one with the right and power and authority to establish advisory committees or panels, and to set up advisory boards, there is no unification, even though you may say there is. When you have three men doing the same work, setting up the same panels, hiring the same experts, then I claim that that is not unification of the armed forces. I wish it were. Does the gentleman think it is? You have three bosses. How can you do it?

Mr. HEBERT. What this bill does is to write into law that which is already the practice under the Unification Act. Let the gentleman not confuse himself in the idea that these three Secretaries will be duplicating their efforts. It means that the three Secretaries are able to obtain the services of the highest scientific skill known in this country, or foreign assistance, if necessary, and they are able to get it, to develop the weapons necessary for each individual branch of the service. By the farthest stretch of the imagination the Secretary of the Navy could not be expected to draw on a scientist in a field that is related to the Army or the Air Force or the development of airplanes if he wanted to find out something about a battleship. This bill allows the Secretaries of the Army, the Air Force, and the Navy to employ the specific specialists and experts and scientists in their particular fields. There is absolutely no duplication of effort. On the contrary, there is a concentration and a unification of effort.

Mr. MILLER of Nebraska. I happen to have some information and knowledge about the so-called ABC program of the Defense Department, that is, the Atomic Energy, Bacterial, and Chemical Warfare Division. Under this each Secretary has a division working with that same lethal weapon, which I think is absolutely necessary. But I am very fearful, in fact, I know they are not coordinating their work. I raise the question that if you are going to have unification there ought to be some coordination of that one particular field. We can go into the field of medicine and cover the whole gauntlet. Men who are working in the Navy, the Air Force, and the Army tell me there is no coordination in their bone grafting, blood transfusions, and other technical things where there should be absolute coordination of the work. Here you are saying to the three Secretaries, "Set up your own division, your own division board, and go your own way." I would like to see just what the gentleman has mentioned, unification where you can bring these scientists all together under one tent, and not under three bosses.

Mr. HEBERT. In reply to the gentleman from Nebraska may I point out the fact that I had the privilege of being present at the Eniwetok atomic experiments and I have never seen such unification, such coordination, such cooperation, and such unity of purpose as I saw at Eniwetok between the three branches of the services, and added to that the inclusion of the civilian branch.

Mr. MILLER of Nebraska. I think that is true. I am glad to know it. But I would feel much better if we would say that the Secretary of Defense, under whom these Secretaries work, might have the authority to set up an advisory committee, which he is already doing and should do, in which he could pool all of these scientists under one tent, under one umbrella, instead of having three sets, as I know they are doing today, going many times in opposite directions and not coordinating their work. That is the thing I objected to. I think it is not in the interest of the public.

Mr. HEBERT. I feel certain this bill will tend toward accomplishing the purpose which both the gentleman and I have in common. I am confident of it.

The bill also provides that the Department of Defense shall be allowed to enter into long-term contracts in the field of research and development. The necessity for this becomes obvious when we realize that so many of the contracts in this field cannot be terminated in a short time and it is necessary that they be spread over a longer period. In addition, the bill also provides that the Department of Defense shall be empowered to employ the services of other than citizens of the United States. I think it is generally recognized that some of the great scientists of this age and day come from other countries. This bill allows them to come into the Department of Defense in research and development, The most important feature of the bill is that section which in effect indemnifies private contractors who are contracted to the Government to conduct these experimental features. I may point out the necessity for this is pointed up perhaps in the development of the supersonic plane by the Bell Airplane Co. In that particular instance it was impossible to indemnify a civilian test pilot, and an Army lieutenant was used to fly that ship on its first flight.

Mr. BROOKS. Mr. Speaker, will the gentleman yield?

Mr. HEBERT. I yield.

Mr. BROOKS. I compliment the gentleman for doing a great job here in handling this bill and having it approved and brought to the House. It is an extremely important bill. I recall in the testimony it was stated that the authority to use scientists is presently in the law. What is wanted now is the authority to use them in committees. They told us at the time this was considered that this would not result in the employment of one single additional individual. That is correct, is it not?

Mr. HEBERT. That is correct. The bill indicates no additional employment of individuals and no additional appropriations. It is merely unifying and codifying the law in connection with present practices. There is no indicated expansion of personnel.

Mr. BROOKS. I am impressed very much with the authority given under this bill to enter into long-term or long-range contracts for experimental work. In my judgment it will not only bring about greater results but will result in greater efficiency and at far less cost to the Government. If anything, I would call this bill a bill to save money and render more efficient service in research work. That is true, is it not?

Mr. HEBERT. The gentleman's interpretation of the bill is correct. This is a bill that unties the hands of the departments and expands them in the field of research and development which is so essential and necessary in this age of scientific warfare. It becomes very important that the Department of Defense be allowed without interference and without any handtying to continue to develop our weapons of war in the scientific field. Of course, No. 1 is the atomic bomb, recoilless weapons and infrarays used in the front lines, and many many other weapons now on the drawing boards and in the scientific laboratories.

The SPEAKER. The time of the gentleman has expired.

The bill was ordered to be engrossed and read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

[p. 9433]

1.14a(3)(b) VOL. 98 (1952), July 3: Amended and passed Senate, pp. 9053–9054

FACILITATION OF RESEARCH AND DEVELOPMENT WORK BY DEPARTMENTS OF ARMY, NAVY, AND AIR FORCE

The bill (H. R. 1180) to facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes was announced as next in order.

Mr. MORSE. Mr. President, I should like to make a brief statement on this bill.

The VICE PRESIDENT. Is the Senator reserving the right to object?

Mr. MORSE. I reserve the right to object.

Mr. President, I make this statement in behalf of the Armed Services Committee: The Senator from Kansas [Mr. SCHOEPPEL] has prepared several amendments to House bill 1180 dealing with research and development work. These amendments are restrictive in nature. However, in examining them, we feel that that there is no reason they should not be accepted by the committee and by the Senate, so that the bill may be passed.

I want to make it clear that we have gone into this matter with the assistance of the professional staff of the Armed Services Committee, and I think the amendments of the Senator from [p. 9053] Kansas should be adopted. I hope he will offer them and that there will be no objection to them.

The VICE PRESIDENT. The question is, Is there objection to the consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Mr. SCHOEPPEL. Mr. President, I call up amendment A, amendment B, and amendment C which were sent to the desk a few days ago, and which I understand are printed.

The VICE PRESIDENT. Does the Senator wish to have them considered en bloc?

Mr. SCHOEPPEL. Yes, Mr. President.

The VICE PRESIDENT. The clerk will state the amendments offered by the Senator from Kansas.

Mr. HAYDEN. Mr. President, may I ask the Senator from Kansas if one of those amendments is to strike out section 7?

Mr. SCHOEPPEL. Amendment C does that.

Mr. HAYDEN. That section should be eliminated, because it interferes with the jurisdiction of the Joint Committee on Printing.

Mr. SCHOEPPEL. That was the view of the Senator from Kansas.

The VICE PRESIDENT. The clerk will state the amendments offered by the Senator from Kansas.

The amendments were:

On page 2, strike out all in lines 7 to 20, inclusive.

On page 4, line 12, after the period, insert the following: "The Secretary of each of the military departments shall transmit to the Congress reports covering contracts for research or development entered into during each 6 months following the enactment of this act. Each such report shall contain (1) a list of each contract for research or development entered into during such period the total cost of which to the Government will exceed $50,000, and (2) specific information with respect to each such contract, except that specific information the disclosure of which he deems incompatible with the security of the United States may be excluded from such reports."

On page 6, strike out all in lines 4 to 12, inclusive.

On page 6, line 13, strike out the section No. "8" and insert in lieu thereof the section No. "7."

Mr. SCHOEPPEL. Mr. President, with reference to amendment A, under section 1 of the bill members of committees and panels and advisory personnel could be exempted from the so-called conflict of interest provisions of title 18, United States Code, relating to Federal officers and employees. The amendment A would strike this provision from the bill.

Amendment B would require that reports be made to Committees on Appropriations and Armed Services of the Senate and of the House of Representatives every 6 months by the Secretary of each of the Military Departments, listing all contracts for research and development in excess of $50,000. Such reports shall contain specific information with respect to any such contract. Provision is made, however, for the exclusion in such reports of specific information pertaining to such contracts which is deemed by the Secretary to be incompatible with the security of the United States.

Amendment C would eliminate from this bill authority to waive certain existing requirements of law with regard to printing in the case of publication of scientific and technical information.

The VICE PRESIDENT. The question is on agreeing en bloc to the amendments offered by the Senator from Kansas.

The amendments were agreed to.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

[p. 9054]

1.14a(3)(c) VOL. 98 (1952), July 4: House concurs in Senate amendments, pp. 9374–9375

RESEARCH AND DEVELOPMENT WORK

Mr. VINSON. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H. R. 1180) to facilitate the performance of research and development work by and on behalf of the Departments of the Army, the Navy, and the Air Force, and for other purposes, with Senate amendments thereto, and concur in the Senate amendments.

The Clerk read the title of the bill.

The Clerk read the Senate amendments, as follows:

Page 2, strike out lines 7 to 20, inclusive.

Page 4, line 12, after "property", insert "The Secretary of each of the military departments shall transmit to the Congress reports covering contracts for research or development entered into during each 6 months following the enactment of this act. Each such report shall contain (1) a list of each contract for research or development entered into during such period the total cost of which to the Government will exceed $50,000, and (2) specific information with respect to each such contract, except that specific information the disclosure of which he deems incompatible with the security of the United States may be excluded from such reports."

Page 6, strike out lines 8 to 16, inclusive.

Page 6, line 17, strike out "8" and insert "7."

The SPEAKER. Is there objection to the request of the gentleman from Georgia?

Mr. ARENDS. Mr. Speaker, reserving the right to object, I do so only for [p. 9374] the purpose of asking the chairman of the Committee on Armed Services to explain to the House these three changes which were made by the other body and agreed to by the conferees.

Mr. VINSON. Mr. Speaker, H. R. 1180 is a bill to facilitate the performance of research and development work by the Army, Navy, and Air Force, passed the House on August 2, 1951. It passed the Senate on July 3, 1952, with three amendments.

The three Senate amendments are restrictive in nature and while the Department would normally not want to agree to those amendments, the time element at present has prompted them to state that the House should agree to the amendments.

Section 1 of the House bill relieved the members of the committees of civilians, which committees were to assist each of the service Secretaries on certain statutory restrictions. For instance, the members of these committees would be permitted to serve with or without compensation and would be exempted from certain statutory prohibitions and penalties which are applicable to all other Federal employees, for example, in regard to the participation in Government contracts or claims against the Government. The net result of the Senate amendment would be that persons who comprise these advisory panels to the Secretaries will probably have to be picked from sources which are not in a contractual relationship with the Government.

The second amendment requires each of the Secretaries to report on research and development contracts involving more than $50,000 each 6 months, unless publication of the information would violate security considerations.

The third amendment deletes section 7 of the bill which authorized the Secretaries of the military departments to arrange for the publication of scientific and technical information resulting from the research and development activities of his Department.

The author of the Senate amendment, Senator SCHOEPPEL, is of the opinion that this printing can be taken care of in a different fashion.

Mr. ARENDS. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER. Is there objection to the request of the gentleman from Georgia [Mr. VINSON]?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

[p. 9375]

1.14b ARMED FORCES PROCUREMENT AMENDMENTS OF 1956

August 10, 1956, P.L. 84–1028, §§2353, 2354, 70A Stat. 134

§ 2353. Contracts: acquisition, construction, or furnishing of test facilities and equipment

(a) A contract of a military department for reasearch or development, or both, may provide for the acquisition or construction by, or furnishing to, the contractor, of research, developmental, or test facilities and equipment that the Secretary of the military department concerned determines to be necessary for the performance of the contract. The facilities and equipment, and specialized housing for them, may be acquired or constructed at the expense of the United States, and may be lent or leased to the contractor with or without reimbursement, or may be sold to him at fair value. This subsection does not authorize new construction or improvements having general utility.

(b) Facilities that would not be readily removable or separable without unreasonable expense or unreasonable loss of value may not be installed or constructed under this section on property not owned by the United States, unless the contract contains—

(1) a provision for reimbursing the United States for the fair value of the facilities at the completion or termination of the contract or within a reasonable time thereafter;

(2) an option in the United States to acquire the underlying land; or

(3) an alternative provision that the Secretary concerned considers to be adequate to protect the interests of the United States in the facilities.

(c) Proceeds of sales or reimbursement under this section shall be paid into the Treasury as miscellaneous receipts, except to the extent otherwise authorized by law with respect to property acquired by the contractor.

§ 2354. Contracts: indemnification provisions

(a) With the approval of the Secretary of the military department concerned, any contract of a military department for research or development, or both, may provide that the United States will indemnify the contractor against either or both of the following, but only to the extent that they arise out of the direct performance of the contract and to the extent not compensated by insurance or otherwise:

(1) Claims (including reasonable expenses of litigation or settlement) by third persons, including employees of the contractor, for death, bodily injury, or loss of or damage to property, from a risk that the contract defines as unusually hazardous.

(2) Loss of or damage to property of the contractor from a risk that the contract defines as unusually hazardous.

(b) A contract, made under subsection (a), that provides for indemnification must also provide for—

(1) notice to the United States of any claim or suit against the contractor for the death, bodily injury, or loss of or damage to property; and

(2) control of or assistance in the defense by the United States, at its election, of that suit or claim.

(c) No payment may be made under subsection (a) unless the Secretary of the department concerned, or an officer or official of his department designated by him, certifies that the amount is just and reasonable. [p. 134]

(d) Upon approval by the Secretary concerned, payments under subsection (a) may be made from—

(1) funds obligated for the performance of the contract concerned;

(2) funds available for research or development, or both, and not otherwise obligated; or

(3) funds appropriated for those payments. [p. 135]

1.14b(1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 970, 84th Cong., 1st Sess. (1955)

REVISION OF TITLE 10, U. S. CODE, ENTITLED "ARMED FORCES", AND TITLE 32, U. S. CODE, ENTITLED "NATIONAL GUARD"

JUNE 28, 1955.—Committed to the Committee of the Whole House on the State of the Union ordered to be printed

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Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 7049]

The Committee on the Judiciary, to whom was referred the bill (H.R. 7049) to revise, codify, and enact into law title 10 of the

United States Code, entitled "Armed Forces", and title 32, United States Code, entitled "National Guard", having considered the same, report favorably thereon and recommend that the bill do pass.

[p. 1]

2. SCOPE

In general, the new title 10, Armed Forces, and the new title 32, National Guard, codify the statutory provisions heretofore reflected in titles 10, 32, and 34, and chapters 3, 7, and 11B of title 5, of the United States Code. All provisions within these areas have been accounted for (see Table 2), whether or not they are codified in the new titles. However, logic and consistency require the exclusion of some laws now codified in the titles and chapters just mentioned, and the inclusion of others now codified elsewhere. Laws of this kind have been accounted for only if included (see Table 2).

[p. 5]

SECTION 2353

Revised Section	Source (U. S. Code)	Source (Statutes at Large)
2353 (a)	5:235e (1st sentence; and 2d sentence, less 2d and last provisos)	July 16, 1952, ch. 882, § 4 (less 3d and last sentences), 66 Stat. 725.
	5:475j (1st sentence; and 2d sentence, less 2d and last provisos)	
	5:628e (1st sentence; and 2d sentence, less 2d and last provisos)	
2353 (b)	5:235e (2d proviso of 2d sentence)	
	5:475j (2d proviso of 2d sentence)	
	5:628e (2d proviso of 2d sentence)	
2353 (c)	5:235e (last proviso of 2d sentence)	
	5:475j (last proviso of 2d sentence)	
	5:628e (last proviso of 2d sentence)	

In subsection (a), the words "furnished to" and "for the use thereof" are omitted as surplusage.

In subsections (a) and (b), the words "United States" are substituted for the word "Government".

In subsection (b), the introductory clause is substituted for 5:235e (words of 2d proviso before clause (1)), 475j, and 628e.

The words "that . . . considers" are substituted for the words "as will in the opinion". The words "an alternative" are substituted for the words "such other".

In subsection (c), the words "Proceeds of" are substituted for the words "That all moneys arising from".

SECTION 2354

Revised Section	Source (U. S. Code)	Source (Statutes at Large)
2354 (a)	5:235f (1st sentence, less provisos)	July 16, 1952, ch. 882, § 5, 66 Stat. 726.
	5:475k (1st sentence, less provisos)	
	5:628f (1st sentence, less provisos)	
2354 (b)	5:235f (1st proviso of 1st sentence)	
	5:475k (1st proviso of 1st sentence)	
	5:628f (1st proviso of 1st sentence)	
2354 (c)	5.235f (last proviso of 1st sentence)	
	5:475k (last proviso of 1st sentence)	
	5:628f (last proviso of 1st sentence)	
2354 (d)	5:235f (less 1st sentence)	
	5.475k (less 1st sentence)	
	5:628f (less 1st sentence)	

In subsection (a), the words "Liability on account of", and "of such claims" are omitted as surplusage. In clauses (1) and (2), the word "from" is substituted for the words "arising as a result of". [p. 139]

1.14b (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 2484, 84th Cong., 2d Sess. (1956)

REVISION OF TITLE 10, UNITED STATES CODE, ENTITLED "ARMED FORCES", AND TITLE 32, UNITED STATES CODE, ENTITLED "NATIONAL GUARD"

JULY 9, 1956.—Ordered to be printed

Mr. O'MAHONEY, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 7049]

The Committee on the Judiciary, to which was referred the bill (H.R. 7049) to revise, codify, and enact into law title 10 of the United States Code, entitled "Armed Forces", and title 32 of the United States Code, entitled "National Guard", having considered the same, reports favorably thereon with amendments and recommends that the bill, as amended, do pass.

[p. 1]

SECTION 2353

Revised Section	Source (U. S. Code)	Source (Statutes at Large)
2353 (a)	5:235e (1st sentence; and 2d sentence, less 2d and last provisos)	July 16, 1952, ch. 882, § 4 (less 3d and last sentences), 66 Stat. 725.
	5:475j (1st sentence; and 2d sentence, less 2d and last provisos)	
	5:628e (1st sentence; and 2d sentence, less 2d and last provisos)	
2353 (b)	5:235e (2d proviso of 2d sentence)	
	5:475j (2d proviso of 2d sentence)	
	5:628e (2d proviso of 2d sentence)	
2353 (c)	5:235e (last proviso of 2d sentence	
	5:475j (last proviso of 2d sentence	
	5:628e (last proviso of 2d sentence	

In subsection (a), the words "furnished to" and "for the use thereof" are omitted as surplusage.

In subsections (a) and (b), the words "United States" are substituted for the word "Government".

In subsection (b), the introductory clause is substituted for 5:235e (words of 2d proviso before clause (1)), 475j, and 628e. The words "that . . . considers" are substituted for the words "as will in the opinion". The words "an alternative" are substituted for the words "such other".

In subsection (e), the words "Proceeds of" are substituted for the words "That all moneys arising from".

SECTION 2354

Revised Section	Source (U. S. Code)	Source (Statutes at Large)
2354 (a)	5:235f (1st sentence, less provisos) 5:475k (1st sentence, less provisos) 5:628f (1st sentence, less provisos)	July 16, 1952, ch. 882, § 5, 66 Stat. 726.
2354 (b)	5:235f (1st proviso of 1st sentence) 5:475k (1st proviso of 1st sentence) 5:628f (1st proviso of 1st sentence)	
2354 (c)	5:235f (last proviso of 1st sentence) 5:475k (last proviso of 1st sentence) 5:628f (last proviso of 1st sentence)	
2354 (d)	5:235f (less 1st sentence) 5:475k (less 1st sentence) 5:628f (less 1st sentence)	

In subsection (a), the words "Liability on account of", and "of such claims" are omitted as surplusage. In clauses (1) and (2), the word "from" is substituted for the words "arising as a result of".

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1.14b (3) CONGRESSIONAL RECORD

1.14b(3)(a) VOL. 101 (1955), Aug. 1: Amended and passed House, pp. 12718–12719

[No Relevant Discussion on Pertinent Section]

1.14b (3) (b) VOL. 102 (1956), July 23: Amended and passed Senate, p. 13953

[No Relevant Discussion on Pertinent Section]

1.14b(3)(c) VOL. 102 (1956), July 25: House concurs in Senate amendment, p. 14455

[No Relevant Discussion on Pertinent Section]

1.15 RULE MAKING, ADMINISTRATIVE PROCEDURE AS REVISED

5 U.S.C. §553 (1966)

[Referred to in 15 U.S.C. §1474(a), (b)]

THE ADMINISTRATIVE PROCEDURE ACT

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule. Pub.L. 89–554, Sept. 6, 1966, 80 Stat. 383.

1.15a RULE MAKING, JUNE 11, 1946, P.L. 97–404, §4, 60 STAT. 238

RULE MAKING

SEC. 4. Except to the extent that there is involved (1) any military, naval, or foreign affairs function of the United States or (2) any matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts—

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(a) NOTICE.—General notice of proposed rule making shall be published in the Federal Register (unless all persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law) and shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(b) PROCEDURES.—After notice required by this section, the agency shall afford interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the agency shall incorporate in any rules adopted a concise general statement of their basis and purpose. Where rules are required by statute to be made on the record after opportunity for an agency hearing, the requirements of sections 7 and 8 shall apply in place of the provisions of this subsection.

(c) EFFECTIVE DATES.—The required publication or service of any substantive rule (other than one granting or recognizing exemption or relieving restriction or interpretative rules and statements of policy) shall be made not less than thirty days prior to the effective date thereof except as otherwise provided by the agency upon good cause found and published with the rule.

(d) PETITIONS.—Every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.

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1.15a (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 752, 79th Cong., 1st Sess. (1945)

ADMINISTRATIVE PROCEDURE ACT

NOVEMBER 19 (legislative day, October 29), 1945.—Ordered to be printed

Mr. MCCARRAN, from the Committee on the Judiciary,
submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7), to improve the administration of justice by prescribing fair administrative procedure, having considered the same, reports favorably thereon, with an amendment, and recommend that the bill do pass, as amended.

There is a widespread demand for legislation to settle and regulate the field of Federal administrative law and procedure. The subject is not expressly mentioned in the Constitution, and there is no recognizable body of such law, as there is for the courts in the Judicial Code. There are no clearly recognized legal guides for either the public or the administrators. Even the ordinary operations of administrative agencies are often difficult to know. The Committee on the Judiciary is convinced that, at least in essentials, there should be some simple and standard plan of administrative procedure.

I. LEGISLATIVE HISTORY

For more than 10 years Congress has considered proposals for general statutes respecting administrative law and procedure. Figure 1 on page 2 presents a convenient chronological chart of the main bills introduced. Each of them has received widespread notice and intense consideration.

The growth of the Government, particularly of the executive branch, has added to the problem. The situation had become such by the middle of the 1930's that the President appointed a committee

[p. 1]

III. STRUCTURE OF THE BILL

The bill, as reported, is not a specification of the details of administrative procedure, nor is it a codification of administrative law. Instead, out of long consideration and in the light of the studies heretofore mentioned, there has been framed an outline of minimum basic essentials. Figure 2 on page 9 diagrams the bill.

The bill is designed to afford parties affected by administrative powers a means of knowing what their rights are and how they may be protected. By the same token, administrators are provided with a simple course to follow in making administrative determinations. The jurisdiction of the courts is clearly stated. The bill thus provides for public information, administrative operation, and judicial review.

SUBSTANCE OF THE BILL.—What the bill does in substance may be summarized under four headings:

1. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law (sec. 3).
2. It states the essentials of the several forms of administrative proceedings (secs. 4, 5, and 6) and the limitations on administrative powers (sec. 9).
3. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings (secs. 7 and 8).
4. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong (sec. 10).

The first of these is basic, because it requires agencies to take the initiative in informing the public. In stating the essentials of the different forms of administrative proceedings, it carefully distinguishes between the so-called legislative functions of administrative agencies (where they issue general regulations) and their judicial functions (in which they determine rights or liabilities in particular cases).

The bill provides quite different procedures for the "legislative" and "judicial" functions of administrative agencies. In the "rule making" (that is, "legislative") function it provides that, with certain exceptions, agencies must publish notice and at least permit interested parties to submit their views in writing for agency consideration before issuing general regulations (sec. 4). No hearings are required by the bill unless statutes already do so in a particular case. Similarly, in "adjudications" (that is, the "judicial" function) no agency hearings are required unless statutes already do so, but in the latter case the mode of hearing [p. 7] and decision is prescribed (sec. 5). Where existing statutes require that either general regulations (called "rules" in the bill) or particularized adjudications (called "orders" in the bill) be made after agency hearing or opportunity for such hearing, then section 7 spells out the minimum requirements for such hearings, section 8 states how decisions shall be made thereafter, and section 11 provides for examiners to preside at hearings and make or participate in decisions.

While the administrative power and procedure provisions of sections 4 through 9 are law apart from court review, the provisions for judicial review provide parties with a method of enforcing their rights in a proper case (sec. 10). However, it is expressly provided that the judicial review provisions are not operative where statutes otherwise preclude judicial review or where agency action is by law committed to agency discretion.

KINDS OF PROVISIONS.—The bill may be said to be composed of five types of provisions:

1. Those which are largely formal such as the sections setting forth the title (sec. 1), definitions (sec. 2), and rules of construction (sec. 12).
2. Those which require agencies to publish or make available information on administrative law and procedure (sec. 3).
3. Those which provide for different kinds of procedures such as rule making (sec. 4), adjudications (sec. 5), and miscellaneous matters (sec. 6) as well as for limitations upon sanctions and powers (sec. 9).
4. Those which provide more of the detail for hearings (sec. 7) and decisions (sec. 8) as well as for examiners (sec. 11).
5. Those which provide for judicial review (sec. 10).

The bill is so drafted that its several sections and subordinate provisions are closely knit. The substantive provisions of the bill should be read apart from the purely formal provisions and minor functional distinctions. The definitions in section 2 are important, but they do not indicate the scope of the bill since the subsequent provisions make many functional distinctions and exceptions. The public information provisions of section 3 are of the broadest application because, while some functions and some operations may not lend themselves to formal procedure, all administrative operations should as a matter of policy be disclosed to the public except as secrecy may obviously be required or only internal agency "housekeeping" arrangements may be involved. Sections 4 and 5 prescribe the basic requirements for the making of rules and the adjudication of particular cases. In each case, where other statutes require opportunity for an agency hearing, sections 7 and 8 set forth the minimum requirements for such hearings and the agency decisions thereafter while section 11 provides for the appointment and tenure of examiners who may participate. Section 6 prescribes the rights of private parties in a number of miscellaneous respects which may be incidental to rule making, adjudication, or the exercise of any other agency authority. Section 9 limits sanctions, and section 10 provides for judicial review.

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Section 1 prescribes the title, section 2 the definitions, and section 3 the effective dates and rules of construction. In the above diagram, the first row of sections sets forth the several kinds of requirements, procedures, and limitations; and the second row includes hearing and decision requirements where other statutes require a hearing. Section 10 on judicial review relates not only to decisions made after agency hearing but, in appropriate cases, to the exercise of any other administrative power or authority.

IV. ANALYSIS OF PROVISIONS

The following statements respecting each provision of the bill are designed to answer specific questions relating to language and objectives. Under each section or subsection heading there appears an italicized synopsis of the provision, followed by one or more paragraphs of analysis or special comment. A reading of all the italicized paragraphs will, therefore, afford a synopsis of the whole bill, which is reproduced at length in appendix A at page 32.

* * * * * * *

[p. 9]

SEC. 4. RULE MAKING.—*The introductory clause exempts from all of the requirements of section 4 any rule making so far as there are involved (1) military, naval, or foreign affairs functions or (2) matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.*

These exceptions would not, of course, relieve any agency from requirements imposed by other statutes. The phrase "foreign affairs functions," used here and in some other provisions of the bill, is not to be loosely interpreted to mean any function extending beyond the borders of the United States but only those "affairs" which so affect relations with other governments that, for example, public rule making provisions would clearly provoke definitely undesirable international consequences. The exception of matters of management or personnel would operate only so far as not inconsistent with other provisions of the bill relating to internal management or personnel. The exception of proprietary matters is included because the principal considerations in most such cases relate to mechanics and interpretations or policy, and it is deemed wise to encourage and facilitate the issuance of rules by dispensing with all mandatory procedural requirements. None of these exceptions, however, is to be taken as encouraging agencies not to adopt voluntary public rule making procedures where useful to the agency or beneficial to the public. The exceptions merely confer a complete discretion upon agencies to decide what, if any, public rule making procedures they will adopt in a given situation within their terms. It should be noted, moreover that the exceptions apply only "to the extent" that the excepted subjects are directly involved.

(a) NOTICE.—*General notice of proposed rule making must be published in the Federal Register and must include (1) time, place,* [p. 13] *and nature of proceedings, (2) reference to authority under which held, and (3) terms, substance, or issues involved. However, except where notice and hearing is required by some other statute, the subsection does not apply to rules other than those of substance or where the agency for good cause finds (and incorporates the finding and reasons therefor in the published rule) that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.*

Agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or argument relating thereto. The subsection governs the application of the public procedures required by the next subsection, since those procedures only apply where notice is required by this subsection. Agencies are given discretion to dispense with notice (and consequently with public proceedings) in the case of interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. This does not mean, however, that agencies should not—where useful to them or helpful to the public—undertake public procedures in connection with such rule making. The exemption of situations of emergency or necessity is not an "escape clause" in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. "Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings. "Unnecessary" means unnecessary so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved. "Public interest" supplements the terms "impracticable" or "unnecessary"; it requires that public rule-making procedures shall not prevent an agency from operating and that, on the other hand, lack of public interest in rule making warrants an agency to dispense with public procedure. It should be noted that where authority beneficial to the public does not become operative until a rule is issued, the agency may promulgate the necessary rule immediately and rely upon supplemental procedures in the nature of a public reconsideration of the issued rule to satisfy the requirements of this section. Where public rule-making procedures are dispensed with, the provisions of subsection (c) and (d) of this section would nevertheless apply.

(b) PROCEDURES.—*After such notice, the agency must afford interested persons an opportunity to participate in the rule making at least to the extent of submitting written data, views, or argument; and, after consideration of such presentations, the agency must incorporate in any rules adopted a concise general statement of their basis and purpose. However, where other statutes require rules to be made after hearing, the requirements of sections 7 and 8 (relating to public hearings and decisions thereon) apply in place of the provisions of this subsection.*

This subsection states, in its first sentence, the minimum requirements of public rule making procedure short of statutory hearing. Under it agencies might in addition confer with industry advisory committees, consult organizations, hold informal "hearings," and the like. Considerations of practicality, necessity, and public interest as discussed in connection with subsection (a) will naturally govern the agency's determination of the extent to which public [p. 14] proceedings should go. Matters of great import, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures. The agency must analyze and consider all relevant matter presented. The required statement of the basis and purpose of rules issued should not only relate to the data so presented but with reasonable fullness explain the actual basis and objectives of the rule.

(c) EFFECTIVE DATES.—*The required publication or service of any substantive rule must be made not less than 30 days prior to its effective date except (1) as otherwise provided by the agency for good cause found and published or (2) in the case of rules recognizing exemption or relieving restriction, interpretative rules, and statements of policy.*

This subsection does not provide procedures alternative to notice and other public proceedings required by the prior subsections of this section. Nor does it supersede the provisions of subsection (d) of this section. Where public procedures are omitted as authorized in certain cases, subsection (c) does not thereby become inoperative. It will afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take any other action which the issuance of rules may prompt. While certain named kinds of rules are not necessarily subject to the deferred effective date provided, it does not thereby follow that agencies are required to make such excepted types of rules operative with less notice or no notice but, instead, agencies are given discretion in those cases to fix such future effective date as they may find advisable. The other exception, upon good cause found and published, is not an "escape clause" which may be arbitrarily exercised but requires legitimate grounds supported in law and fact by the required finding. Moreover, the specification of a 30-day deferred effective date is not to be taken as a maximum, since there may be cases in which good administration or the convenience and necessity of the persons subject to the rule reasonably requires a longer period.

(d) PETITIONS.—*Every agency is required to accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.*

This subsection applies not merely to effective rules existing at any time but to proposed or tentative rules. Where the latter are published, agencies should receive petitions for modification because that is one of the purposes of publishing proposed or tentative rules. Where such petitions are made, the agency must fully and promptly consider them, take such action as may be required, and pursuant to section 6(d) notify the petitioner in case the request is denied. The agency may either grant the petition, undertake public rule making proceedings as provided by subsections

(a) and (b) of this section, or deny the petition. The taking or denial of action would have the same effect and consequences as the taking or denial of action where, under presently existing legislation, the equivalent of a right of petition is recognized in interested persons. The mere filing of a petition does not require an agency to grant it, or to hold a hearing, or engage in any other public rule making proceedings. The refusal of an agency to grant the petition or to hold rule making proceedings, therefore, would not per se be subject to judicial reversal. However, the facts or considerations brought to the attention of agency by such a petition might be such as to require the agency to act to prevent

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the rule from continuing or becoming vulnerable upon judicial review, through declaratory judgment or other procedures pursuant to section 10.

SEC. 5. ADJUDICATIONS.—*The various subsequent provisions of section 5 relating to adjudications apply only where the case is otherwise required by statute to be determined upon an agency hearing except that, even in that case, the following classes of operations are expressly not affected: (1) Cases subject to trial de novo in court, (2) selection or tenure of public officers other than examiners, (3) decisions resting on inspections, tests, or elections, (4) military, naval, and foreign affairs functions (5) cases in which an agency is acting for a court, and (6) the certification of employee representatives.*

The general limitation of this section to cases in which other statutes require the agency to act upon or after a hearing is important. All cases are nevertheless subject to sections 2, 3, 6, 9, 10, and 12 so far as those are otherwise relevant.

The numbered exceptions remove from the operation of the section even adjudications otherwise required by statute to be made after hearing. The first, where the adjudication is subject to a judicial trial de novo, is included because whatever judgment the agency makes is effective only in a prima facie sense at most and the party aggrieved is entitled to complete judicial retrial and decision. The second, respecting the selection and tenure of officers other than examiners, is included because the selection and control of public personnel has been traditionally regarded as a discretionary function which, if to be overturned, should be done by separate legislation. The third exempts proceedings resting on inspections, tests, or elections because those methods of determination do not lend themselves to the hearing process. The fourth exempts military, naval, and foreign affairs functions for the same reasons that they are exempted from section 4; and in any event, rarely if ever do statutes require such functions to be exercised upon hearing. The fifth, exempting cases in which an agency is acting as the agent for a court, is included because the administrative operation is subject to judicial revision in toto. The sixth, exempting the certification of employee representatives such as the Labor Board operations under section 9(c) of the National Labor Relations Act, is included because these determinations rest so largely upon an election or the availability of an election. It should be noted that these exceptions apply only "to the extent" that the excepted subject is involved and, it may be added, only to the extent that such subjects are directly involved.

(a) NOTICE.—*Persons entitled to notice of an agency hearing are to be duly and timely informed of (1) the time, place, and nature of the hearing, (2) the legal authority and jurisdiction under which it is to be held, and (3) the matters of fact and law asserted. Where private persons are the moving parties, respondents must give prompt notice of issues controverted in law or fact; and in other cases the agency may require responsive pleading. In fixing the times and places for hearings the agency must give due regard to the convenience and necessity of the parties.*

The specification of the content of notice, so far as legal authority and the issues are concerned, does not mean that prior to the commencement of the proceedings an agency must anticipate all developments and all possible issues. But it does mean that, either by the formal notice or otherwise in the record, it must appear that the party [p. 16]

Rule Making

Sec. 4. Except to the extent that there is involved (1) any military, naval, or foreign affairs function of the United States or (2) any matter relating to agency management or personnel or to public property, loans, grants, benefits or contracts—

(a) Notice.—General notice of proposed rule making shall be published in the Federal Register and shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(b) Procedures.—After notice required by this section, the agency shall afford interested persons an opportunity to participate in the rule making through submission of written data, views, or argument with or without oppor-

tunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the agency shall incorporate in any rules adopted a concise general statement of their basis and purpose. Where rules are required by law to be made upon the record after opportunity for or upon an agency hearing, the requirements of sections 7 and 8 shall apply in place of the provisions of this subsection.

(c) Effective Dates.—The required publication or service of any substantive rule (other than one granting or recognizing exemption or relieving restriction or interpretative rules and statements of policy) shall be made not less than thirty days prior to the effective date thereof except as otherwise provided by the agency upon good cause found and published with the rule.

(d) Petitions.—Every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule. [p. 33]

Section 4. The term "naval" in the first exception clause is intended to include the defense functions of the Coast Guard and the Bureau of Marine Inspection and Navigation.

Section 4 (b), in requiring the publication of a concise general statement of the basis and purpose of rules made without formal hearing, is not intended to require an elaborate analysis of rules or of the detailed considerations upon which they are based but is designed to enable the public to obtain a general idea of the purpose of, and a statement of the basic justification for, the rules. The requirement would also serve much the same function as the whereas clauses which are now customarily found in the preambles of Executive orders. [p. 39]

Section 4 (c): This subsection is not intended to hamper the agencies in cases in which there is good cause for putting a rule into effect immediately, or at some time earlier than 30 days. The section requires, however, that where an earlier effective date is desired the agency should make a finding of good cause therefor and publish its finding along with the rule.

Section 4 (d) simply permits any interested person to petition an agency for the issuance, amendment, or repeal of a rule. It requires the reception and consideration of petitions but does not compel an agency to undertake any rule-making procedure merely because a petition is filed. [p. 40]

1.15a (2) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946)

ADMINISTRATIVE PROCEDURE ACT

MAY 3, 1946.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

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Mr. WALTER, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7) to improve the administration of justice by prescribing fair administrative procedure, having considered the same, report the bill favorably to the House, with an amendment, with the recommendation that, as amended, the bill do pass.

The committee amendment is as follows:

Strike out all of the bill after the enacting clause and insert in lieu thereof the following:

TITLE

SECTION 1. This Act may be cited as the "Administrative Procedure Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) AGENCY.—"Agency" means each authority (whether or not within or subject to review by another agency) of the Government of the United States other than Congress, the courts, or the governments of the possessions, Territories, or the District of Columbia. Nothing in this Act shall be construed to repeal delegations of authority as provided by law. Except as to the requirements of section 3, there shall be excluded from the operation of this Act (1) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them, (2) courts martial and military commissions, (3) military or naval authority exercised in the field in time of war or in occupied territory, or (4) functions which by law expire on the termination of present hostilities, within any fixed period thereafter, or before July 1, 1947, and the functions conferred by the following statutes: Selective Training and Service Act of 1940; Contract Settlement Act of 1944; Surplus Property Act of 1944.

(b) PERSON AND PARTY.—"Person" includes individuals, partnerships, corporations, associations, or public or private organizations of any character other than agencies. "Party" includes any person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in any agency proceeding; but nothing herein shall be construed to prevent an agency from admitting any person or agency as a party for limited purposes.

[p. 1]

(c) RULE AND RULE MAKING.—"Rule" means the whole or any part of any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure, or practice requirements of any agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor, or of valuations, costs, or accounting, or practices bearing upon any of the foregoing. "Rule making" means agency process for the formulation, amendment, or repeal of a rule.

(d) ORDER AND ADJUDICATION.—"Order" means the whole or any part of the final disposition (whether affirmative, negative, injunctive, or declaratory in form) of any agency in any matter other than rule making but including licensing. "Adjudication" means agency process for the formulation of an order.

(e) LICENSE AND LICENSING.— "License" includes the whole or part of any agency permit, certificate, approval, registration, charter, membership, statutory exemption, or other form of permission. "Licensing" includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license.

(f) SANCTION AND RELIEF.—"Sanction" includes the whole or part of any agency (1) prohibition, requirement, limitation, or other condition affecting the freedom of any person; (2) withholding of relief; (3) imposition of any form of penalty or fine; (4) destruction, taking, seizure, or withholding of property; (5) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees; (6) requirement, revocation, or suspension of a license; or (7) taking of other compulsory or restrictive action. "Relief" includes the whole or part of any agency (1) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy; (2) recognition of any claim, right, immunity, privilege, exemption, or exception; or (3) taking of any other action upon the application or petition of, and beneficial to, any person.

(g) AGENCY PROCEEDING AND ACTION.—"Agency proceeding" means any agency process as defined in subsections (c), (d), and (e) of this section. "Agency action" includes the whole or part of every agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.

PUBLIC INFORMATION

SEC. 3. Except to the extent that there is involved (1) any function of the United States requiring secrecy in the public interest or (2) any matter relating solely to the internal management of an agency—

(a) RULES.—Every agency shall separately state and currently publish in the Federal Register (1) descriptions of its central and field organization including delegations by the agency of final authority and the established places at which, and methods whereby, the public may secure information or make submittals or requests; (2) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal or informal procedures available as well as forms and instructions as to the scope and contents of all papers, reports, or examinations; and (3) substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law. No person shall in any manner be required to resort to organization or procedure not so published.

(b) OPINIONS AND ORDERS.—Every agency shall publish or, in accordance with published rule, make available to public inspection all final opinions or orders in the adjudication of cases (except those required for good cause to be held confidential and not cited as precedents) and all rules.

(c) PUBLIC RECORDS.—Save as otherwise required by statute, matters of official record shall in accordance with published rule be made available to persons properly and directly concerned except information held confidential for good cause found.

RULE MAKING

SEC. 4. Except to the extent that there is involved (1) any military, naval, or foreign affairs function of the United States or (2) any matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts—

> (a) NOTICE.—General notice of proposed rule making shall be published in the Federal Register (unless all persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with [p. 2] law) and shall include (1) a statement of the time, place, and nature of public rule-making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.
>
> (b) PROCEDURES.—After notice required by this section, the agency shall afford interested persons an opportunity to participate in the rule making through submission of written data, views, or argument with or without opportunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the agency shall incorporate in any rules adopted a concise general statement of their basis and purpose. Where rules are required by statute to be made on the record after opportunity for an agency hearing, the requirements of sections 7 and 8 shall apply in place of the provisions of this subsection.
>
> (c) EFFECTIVE DATES.—The required publication or service of any substantive rule (other than one granting or recognizing exemption or relieving restriction or interpretative rules and statements of policy) shall be made not less than thirty days prior to the effective date thereof except as otherwise provided by the agency upon good cause found and published with the rule.
>
> (d) PETITIONS.—Every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule. [p. 3]

III. THE SUBSTANCE OF THE BILL

Manifestly the bill does not unduly encroach upon the needs of any legitimate government operation, although it is of course operative according to its terms even if it should cause some administrative inconvenience or changes in procedure. It is brief, but necessarily not oversimplified. Functional classifications and exemptions have been made, but in no part of the bill is any agency exempted by name. The bill is meant to be operative "across the board" in accordance with its terms, or not at all. Where one agency has been able to demonstrate that it should be exempted, all like agencies have been exempted in general terms. (See sec. 2 (a)). Where one agency has shown that some particular operation should be exempted from any particular requirement, the same function in all agencies has been exempted. No agency has been favored by special treatment.

The bill is an outline of minimum essential rights and procedures. Agencies may fill in details, so long as they publish them. It

affords private parties a means of knowing what their rights are and how they may protect them, while administrators are given
[p. 16]
a simple framework upon which to base such operations as are subject to the provisions of the bill.

What the bill does in substance may be summarized under four headings: 1. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law (sec. 3). 2. It states the essentials of the several forms of administrative proceedings (secs. 4, 5, and 6) and the general limitations on administrative powers (sec. 9). 3. It provides in more detail the requirements for administrative hearings and decisions in cases in whch statutes require such hearings (secs. 7 and 8). 4. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong (sec. 10).

The public information section is basic, because it requires agencies to take the initiative in informing the public. In stating the essentials of the different forms of administrative proceedings, the bill carefully distinguishes between the so-called legislative functions of administrative agencies (where they issue general regulations) and their judicial functions (in which they determine rights or liabilities in particular cases). It provides quite different procedures for the "legislative" and "judicial" functions of administrative agencies. In the "rule making" (that is, "legislative") function it provides that with certain exceptions agencies must publish notice and at least permit interested parties to submit their views in writing for agency consideration before the issuance of general regulations (sec. 4). No hearings are required by the bill unless statutes already do so in a particular case. Similarly, in "adjudications" (that is, the "judicial" function) no agency hearings are required unless statutes already do so, but in the latter case the mode of hearing and decision is prescribed (sec. 5). Where existing statutes require that either general regulations (called "rules" in the bill) or particularized adjudications (called "orders" in the bill) be made after agency hearing or opportunity for such hearing, then section 7 spells out the minimum requirements for such hearings, section 8 states how decisions shall be made thereafter, and section 11 provides for examiners to preside at hearings and make or participate in decisions.

While the administrative power and procedure provisions of sections 4 through 9 are law apart from court review, the provisions for judicial review afford parties a method of enforcing their rights in proper cases (sec. 10). However, it is expressly provided that the judicial-review provisions are not operative where statutes otherwise preclude judicial review or where agency action is by law committed to agency discretion.

The bill is so drafted that its several sections and subordinate provisions are closely knit. The operative provisions of the bill should be read apart from the purely formal provisions and minor functional distinctions. The definitions in section 2 are important, but they do not indicate the scope of the bill since the subsequent provisions make many functional distinctions and exceptions. The public-information provisions of section 3 are of the broadest application because, while some functions and some operations may not lend themselves to formal procedure, all administrative operations should as a matter of policy be disclosed to the public except as

[p. 17]

secrecy may obviously be required or only internal agency "housekeeping" arrangements may be involved. Sections 4 and 5 prescribe the basic requirements for the making of rules and the adjudication of particular cases. In each case, where other statutes require opportunity for an agency hearing, sections 7 and 8 set forth the minimum requirements for such hearings and the agency decisions thereafter while section 11 provides for the appointment and tenure of examiners who may participate. Section 6 prescribes the rights of private parties in a number of miscellaneous respects which may be incidental to rule making, adjudication, or the exercise of any other agency authority. Section 9 limits sanctions, and section 10 provides for judicial review.

A diagram of the bill is to be found at pages 28–29 of this report.

IV. EXPLANATION OF PROVISIONS

In the following explanation, under each section heading there appears an italicized synopsis of the provision and a paragraph or more of analysis or comment. The chart on pages 28 and 29 provides a diagrammed synopsis of the bill. The full bill is reproduced as appendix A hereto, which also shows the clarifications it makes in the similar Senate bill.

[p. 18]

SECTION 4. RULE MAKING

The introductory clause exempts from all of the requirements of section 4 any rule making so far as there are involved (1) military, naval, or foreign-affairs functions or (2) matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

The principal purpose of this section is, where other statutes do not require a hearing, to provide that the legislative functions of administrative agencies shall so far as possible be exercised only upon public participation on notice as provided in sections 4 (a) and (b).

The introductory exceptions to the section do not relieve an agency from any requirements imposed by law apart from this bill. They apply only "to the extent" that the excepted subject matter is clearly and directly involved. The phrase "foreign affairs functions," used here and in some other provisions of the bill, is not to be loosely interpreted to mean any agency operation merely because it is exercised in whole or part beyond the borders of the United States but only those "affairs" which so affect the relations of the United States with other governments that, for example, public rule-making provisions would provoke definitely undesirable international consequences. The exception of matters of management or personnel would operate only so far as not inconsistent with other provisions of the bill relating to those matters. The term "public property" would include property held by the United States in trust or as guardian, as Indian property is often held. The exception of proprietary matters is included because a main consideration in such cases relates to mechanics, interpretations, or policy and it is wise to encourage and facilitate the issuance of rules by dispensing with all mandatory procedural requirements. Changes can then be sought through the petition procedures of section 4(d), by which such rule making may also be initially invoked. But these exceptions are not to be taken as encouraging agencies not to adopt voluntary public rule-making procedures where useful to the agency or beneficial to the public. They merely confer a discretion upon agencies to decide what, if any, public rule-making procedures shall be utilized in a given situation within their terms. [p. 23]

SECTION 4 (A). NOTICE OF RULE MAKING

General notice of proposed rule making must be published in the Federal Register—unless all persons subject to the rules are named and are personally served or otherwise have actual notice as provided by law—and must include (1) the time, place, and nature of proceedings, (2) reference to the authority under which held, and (3) the terms, substance, or issues involved. However, except where notice and hearing is required by some other statute, the section does not apply to rules other than those of substance or where the agency for good cause finds (and incorporates the finding and reasons therefor in the published rule) that notice and *public procedure are impracticable, unnecessary, or contrary to the public interest.*

The provisions respecting the fullness of notice apply whether or not, under the terms of the section, it must be published in the Federal Register. Notice must fairly apprise interested persons of the issues involved, so that they may present relevant data or argument. The required specification of legal authority must be done with particularity. Statements of issues in the general statutory language of legislative delegations of authority to the agency would not be a compliance with the section. Prior to public procedures agencies must conduct such nonpublic studies or investigations as will enable them to formulate issues, or where possible to issue proposed or tentative rules for the purpose of public proceedings. Summaries and reports may also be issued as aids in securing public comment or suggestions.

The section governs the application of the public procedures required by section 4(b) since those procedures only apply where notice is required by this section. Agencies are given discretion to dispense with notice (and consequently with public proceedings) in the case of interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; but this does not mean that they should not undertake public procedures in connection with such rule making where useful to them or helpful to the public. The exemption of situations of emergency or necessity is not an "escape clause" in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. "Impracticable" means a situation in which the due, timely, and required execution of agency functions would be unavoidably prevented by its undertaking public rule-making proceedings. "Unnecessary" means so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved. "Public interest" supplements the terms "impracticable" or "unnecessary"; it requires that public rule-making procedures shall not unreasonably prevent an agency from fulfilling its duty and that, on the other hand, lack of public concern in rule making warrants an agency to dispense with public procedure. Where authority beneficial to the public does not become operative until a rule is issued, the agency may promulgate the necessary rule immediately and rely upon supplemental procedures in the nature of a public reconsideration of the issued rule to satisfy the requirements of

[p. 24]

this section. Where public rule-making procedures are dispensed with, the provisions of subsections (c) and (d) of this section would nevertheless apply. Notice otherwise required by law apart from this bill is not repealed or diminished by this section.

SECTION 4 (B). PUBLIC PROCEDURES IN RULE MAKING

After such notice, the agency must afford interested persons an opportunity to participate in the rule making at least to the extent of submitting written data, views, or argument; and, after consideration of such presentations, the agency must incorporate in any rules adopted a concise general statement of their basis and purpose. However, where other statutes require rules to be made after opportunity for hearing, the requirements of sections 7 and 8 (relating to public hearings and decisions thereon) apply in place of the provisions of this subsection.

The first sentence states the minimum requirements of public rule-making procedure short of statutory hearing. Under it agencies might in addition confer with industry advisory committees, consult organizations, hold informal "hearings," and the like. Open proceedings may be aided by the submission of reports or summaries of data by agency representatives. Where open proceedings are held, interested persons unable to be present would be entitled to make written submittals. Considerations of practicality, necessity, and public interest as discussed in connection with section 4 (a) will naturally govern the agency's determination of the extent to which public proceedings may be carried. Matters of great import, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures. The agency must keep a record and analyze and consider all relevant matter presented prior to the issuance of rules. The required statement of the basis and purpose of rules issued should not only relate to the data so presented but with reasonable fullness explain the actual basis and objectives of the rule.

These rule-making procedures must be incorporated in the rules published pursuant to section 3 (a), although their applicability may be left to the notice of rule making in a given case and modifications or extensions of procedure may be made in the notice.

SECTION 4 (C). FUTURE EFFECTIVE DATE OF RULES

The required publication or service of any substantive rule must be made not less than 30 days prior to its effective date except (1) as otherwise provided by the agency for good cause found and published or (2) in the case of rules recognizing exemption or relieving *restriction, interpretative rules, and statements of policy.*

This section does not repeal or diminish other time requirements provided by law apart from this bill. It does not provide procedures alternative to notice and other public proceedings required by the prior sections. Nor does it supersede the provisions of section 4 (d). Where public procedures are omitted as authorized in certain cases, section 4 (c) does not thereby become inoperative. It will afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take any other action which the issuance of rules may prompt. The specification of a 30-day deferred effective [p. 25] date is not to be taken as a maximum, since there may be cases in which good administration or the convenience and necessity of the persons subject to the rule reasonably require a longer period. While certain named kinds of rules are not necessarily subject to the deferred effective date provided, it does not thereby follow that agencies are required to make such excepted types of rules operative with less notice or no notice but, instead, agencies may fix such future effective date as is advisable. The other exception—upon good cause found and published—is not an "escape clause" which may be exercised at will but requires legitimate grounds supported in law and fact by the required finding. Many rules, such as some agricultural marketing "orders," may be made operative in less than 30 days because of inescapable or unavoidable limitations of time, because of the demonstrable urgency of the conditions they are designed to correct, and because the parties subject to them may during the usually protracted hearing and decision procedures anticipate the regulation. In any event, however, no rule requiring action may be made effective until a legally reasonable time after its issuance as judged in the light of all the circumstances.

SECTION 4 (D). PETITIONS RESPECTING RULES

Every agency is required to accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.

This section applies not merely to effective rules existing at any time but to proposed or tentative rules. Where such petitions are made, the agency must fully and promptly consider them, take such action as may be required, and pursuant to section 6 (d) notify the petitioner in case the request is denied. The agency may either grant the petition, undertake public rule-making proceedings as provided by sections 4 (a) and 4 (b), or deny the petition. The mere filing of a petition does not require an agency to grant it, or to hold a hearing, or to engage in other public rule-making proceedings. But the agency must act on the petition in accordance with procedures set up and published in compliance with section 3 (a). [p. 26]

QUASI-LEGISLATIVE FUNCTIONS

SEC. 4. Rule Making.—Except war, foreign affairs, management, and proprietary functions: (a) notice of rule making is to be published in certain instances, (b) thereafter interested persons are to be permitted to make at least written submittals for agency consideration, except that if other statutes require an agency hearing then sections 7 and 8 apply, (c) effective date of rules is to be 30 days following publication, and (d) any interested person may petition for issuance, amendment, or repeal of a rule. [p. 29]

RULE MAKING

SEC. 4. Except to the extent that there is involved (1) any military, naval, or foreign affairs function of the United States or (2) any matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts—

(a) NOTICE.—General notice of proposed rule making shall be published in the Federal Register (*unless all persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law*)[8] and shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(b) PROCEDURES.—After notice required by this section, the agency shall afford interested persons an opportunity to participate in the rule making through submission of written data, views, or argument with or without opportunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the agency shall incorporate in any rules adopted a concise general statement of their basis and purpose. Where rules are required by [law] *statute* to be made [upon] *on* the record after opportunity for [or upon][9] an agency hearing, the requirements of sections 7 and 8 shall apply in place of the provisions of this subsection.

(c) EFFECTIVE DATES.—The required publication or service of any substantive rule (other than one granting or recognizing exemption or relieving restriction or interpretative rules and statements of policy) shall be made not less than thirty days prior to the effective date thereof except as otherwise provided by the agency upon good cause found and published with the rule.

(d) PETITIONS.—Every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule. [p. 51]

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[8] The added language supplements the changes explained in notes 6 and 7. There is no reason to burden the Federal Register with notices addressed to particular parties who have been personally served or otherwise have notice.

[9] The change is made to conform to the language used in the introductory clause of section 5 respecting adjudications. A statute may, in terms, require a rule or order to be made upon the record of a hearing, or in the usual case be interpreted as manifesting a Congressional intention so to require, and in either situation sections 7 and 8 would apply save as other exceptions are operative.

1.15a (3) CONGRESSIONAL RECORD, VOL. 92 (1946)

1.15a(3)(a) March 12: Debated, amended and passed Senate, pp. 2151–2152, 2155, 2157, 2161–2162, 2165

Mr. McCARRAN.

* * * * *

To state it simply, this bill is designed to afford parties affected by administrative powers a means of knowing what their rights are, and how they may be protected. At the same time, administrators are provided with a simple course to follow in making administrative determinations. The jurisdiction of the courts is clearly stated. The bill thus provides for public information, administrative operation, and judicial review.

The substance of what the bill does may be summarized under four headings:

First: It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law.

Second. It states the essentials of the several forms of administrative proceedings and the limitations on administrative powers.

Third. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings.

Fourth. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong.

The first of those four points is basic, because it requires agencies to take the initiative in informing the public. In stating the essentials of the different forms of administrative proceedings, the bill carefully distinguishes between the so-called legislative functions of administrative agencies—where they issue general regulations—and their judicial functions—in which they determine rights or liabilities in particular cases.

Quite different procedures are provided by the bill for the legislative and judicial functions of administrative agencies. In the rule-making, that is, legislative, function the bill provides that, with certain exceptions, agencies must publish notice and at least permit interested parties to submit their views in writing for agency consideration before issuing general regulations. No hearings are required by the bill unless statutes already do so in a particular case. Similarly, in adjudications—that is, the judicial function—no agency hearings are required unless statutes already do so, but in the latter case the mode of hearing and decision is prescribed. Where existing statutes require that either general regulations—which the bill calls rules—or particularized adjudications—which the bill calls orders—shall be made after agency hearing or opportunity for such hearing, then section 7 of the bill spells out the minimum requirements for such hearings; section 8 states how decisions shall be made thereafter, and section 11 provides for examiners to preside at hearings and make or participate in decisions.

While the administrative power and procedure provisions of sections 4, 5, 6, 7, 8, and 9 are law apart from court review, the provisions for judicial review provide parties with a method of enforcing their rights in a proper case. However, it is expressly provided that the judicial review provisions are not operative where statutes otherwise preclude judicial review, or where agency action is by law committed to agency discretion.

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[p. 2151]

Sections 4 and 5 of the bill prescribe the basic requirements for the making of rules and the adjudication of particular cases. In each case, where other statutes require opportunity for an agency hearing, sections 7 and 8 set forth the minimum requirements for such hearings and the agency decisions thereafter, while section 11 provides for the appointment and tenure of examiners who may participate. Section 6 prescribes the rights of private parties in a number of miscellaneous respects which may be incidental to rule making, adjudication, or the exercise of any other agency authority. Section 9 limits sanctions, and section 10 provides for judicial review.

* * * * *

The term "rule making" is defined to mean agency process for the formulation, amendment, or repeal of a rule, and includes any prescription for the future of rates, wages, financial structures, and so on.

The term "order" is defined to mean the final disposition of any matter, other than rule making but including licensing, whether or not affirmative, negative, or declaratory in form.

[p. 2152]

The definitions of the Walter-Logan bill were imperfect and confusing. Rules were so defined as to include "orders" and were limited to interpretations of terms of statutes. That bill, therefore, failed to distinguish between substantive, interpretive, and procedural rules. The pending bill exempts from its procedural requirements all interpretive, organizational, and procedural rules, because under present law interpretive rules, being merely adaptations of interpretations of statutes, are subject to a more ample degree of judicial review, and because the problem with respect to the other exempted types of rules is to facilitate their issuance rather than to supply procedures.

* * * * *

Section 4 concerns rule making. The introductory clause exempts from all of the requirements of section 4 any rule making, so far as there are involved military, naval, or foreign affairs functions, or matters relating to agency management or personnel, or to public property, loans, grants, benefits, or contracts.

Mr. President, I wish the Senate would give close consideration to what I am about to discuss, because it is all important.

Subsection (a) of section 4 concerns notice. It provides that general notice of proposed rule making must be published in the Federal Register and must include the time, place, and nature of the proceedings, a reference to the authority under which such proceedings are held, and the terms, substance, or issues involved. However, except where notice and hearing is required by some other statute, the subsection does not apply to rules other than those of substance, or where the agency for good cause finds, and incorporates the finding and reasons therefor in the published rule, that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

Subsection (b) of section 4 concerns procedures. This subsection provides that after such notice as required by the preceding subsection, the agency must afford interested persons an opportunity to participate in the rulemaking, at least to the extent of submitting written data, views, or argument. This subsection also provides that after consideration of such presentations, the agency must incorporate in any rules adopted a concise general statement of their basis and purpose. However, where other statutes require rules to be made after hearing, the requirements of sections 7 and 8, which relate to public hearings and decisions thereon, apply in place of the provisions of this subsection.

Subsection (c) of section 4 refers to effective dates. The required publication or service of any substantive rule must, under this provision, be made not less than 30 days prior to the effective date of such rule, except as otherwise provided by the agency for good cause found and published, or, in the case of rules recognizing exemption or relieving restriction, interpretative rules, and statements of policy.

Subsection (d) of section 4 concerns petitions, and provides that every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.

[p. 2155]

Section 7 concerns hearings and applies only where hearings are required by section 4 or 5.

[p. 2157]

Mr. JOHNSON of Colorado.

* * * * *

The proposed act is said by its drafters to be designed to achieve four essential and simple purposes:

"(1) It requires administrative agencies to publish their organizations and procedures, and to make available to public inspection their orders and releases.

"(2) As to rule making, it requires that agencies publish notice and at least permit interested parties to submit views or data for consideration.

"(3) As to adjudication, it provides that, in the absence of agreement through informal methods, agencies must accord the parties notice, hearing, and decision before responsible officers, with provision for the segregation of deciding and prosecuting functions.

"(4) As to judicial review, it provides forms of review actions for the determination of all questions of law in all matters not expressly committed to executive discretion."

The short title of the act is given as the "Administrative Procedure Act."

[p. 2161]

Section 4 of the proposed act covers the subject of "adjudication" and provides that in every case of administrative adjudication in which the rights, duties, obligations, privileges, benefits, or other legal relations of any person are required to be determined only after opportunity for an administrative hearing (except to the extent that if there is directly involved any matter subject to a subsequent trial of the law and facts de novo in any court notice shall be given [subsec. (a)]).

The introductory double exception to the section removes from the operations of sections 4, 5, and 7 all administrative procedures in which the law concerned does not require rules or orders to be made upon a hearing and all matters subject to a subsequent trial de novo in any court.

[p. 2162]

[Committee amended bill]

* * * * *

RULE MAKING

SEC. 4. Except to the extent that there is involved (1) any military, naval, or foreign affairs function of the United States or (2) any matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts—

(a) Notice: General notice of proposed rule making shall be published in the Federal Register and shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, or in any situation in which the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(b) Procedures: After notice required by this section, the agency shall afford interested persons an opportunity to participate in the rule making through submission of written data, views, or argument with or without opportunity to present the same orally in any manner; and, after consideration of all relevant matter presented, the agency shall incorporate in any rules adopted a concise general statement of their basis and purpose. Where rules are required by law to be made upon the record after opportunity for or upon an agency hearing, the requirements of sections 7 and 8 shall apply in place of the provisions of this subsection.

(c) Effective dates: The required publication or service of any substantive rule (other than one granting or recognizing exemption or relieving restriction or interpretative rules and statements of policy) shall be made not less than 30 days prior to the effective date thereof except as otherwise provided by the agency upon good cause found and published with the rule.

(d) Petitions: Every agency shall accord any interested person the right to petition for the issuance, amendment, or repeal of a rule.

[p. 2165]

1.15a(3)(b) May 24: Debated, amended and passed House, pp. 5645, 5649, 5650–5651, 5656, 5660–5661

ADMINISTRATIVE PROCEDURE ACT

Mr. SABATH. Mr. Speaker, I call up House Resolution 615 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

> *Resolved*, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the act (S. 7) to improve the administration of justice by prescribing fair administrative procedure. That after general debate, which shall be confined to the act and continue not to exceed 2 hours, to be equally divided and controlled by the chairman and the ranking minority member of the Committee on the Judiciary, the act shall be read for amendment under the 5-minute rule. At the conclusion of the consideration of the act for amendment, the Committee shall rise and report the act to the House with such amendments as may have been adopted and the previous question shall be considered as ordered on the act and amendments thereto to final passage without intervening motion except one motion to recommit.

TO IMPROVE ADMINISTRATIVE PROCEDURE

Mr. SABATH. Mr. Speaker, later on I shall yield 30 minutes to the gentleman from Michigan [Mr. MICHENER].

Mr. Speaker, House Resolution 615 makes in order the consideration of Senate 7 as amended by the Committee on the Judiciary. The bill aims to improve the administration of justice by prescribing fair administrative procedure. The rule is an open rule, and provides for 2 hours of general debate.

Mr. Speaker, I hope this is only the beginning of legislation to improve the administration of justice and that it will bring out real justice to all those who are obliged to face our courts.

* * * * *

What the bill does, in substance, may be summarized under four headings:

First. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law.

Second. It states the essentials of the several forms of administrative proceedings and the general limitations on administrative powers.

Third. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings.

Fourth. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong.

[p. 5645]

But this bill does more than merely analyze the administrative process and lay down the forms of procedure for each. It really deals with three separate subjects: First, public information; second, administrative operation; and third, judicial review.

The first operative section of the bill is basic and requires agencies to issue certain information which is essential to inform the public about the substance and the procedure of administrative law. It requires that agencies state their organizational set-ups, promulgate statements respecting their procedures, and make available as regulations the substantive and interpretative rules which they have framed for the guidance of the public.

Sections 4, 5, 6, 8, 9, and 11 deal with administrative operations. Section 4 relates to the legislative functions of administrative agencies and provides that where Congress has not required hearings, with some exceptions, the agency shall give notice of the making of proposed regulations and afford interested parties an opportunity for the informal submission and consideration of their views or requests. Section 5 deals with administrative adjudications of particular cases where Congress has required adjudications to be made upon a hearing. Sections 7, 8, and 11 spell out the details of hearing and decision procedures in all cases in which, by other legislation, Congress has required an agency hearing. Section 9 states certain limitations upon the penalties or relief which agencies may impose or confer in any case. Section 6 deals with the investigative powers and other incidental matters of importance.

In the all-important field of judicial review section 10 is a complete statement of the subject. It prescribes briefly when there may be judicial review and how far the courts may go in examining into a given case.

I shall discuss all these matters in greater detail next in taking up the bill section by section, subsection by subsection.

[p. 5649]

RULE MAKING, SECTION 4

Section 4 deals with the very important subject of rule making. From it, however, are exempted: First, military, naval, or foreign affairs functions; and second, matters relating to agency management or personnel or to public property, loans, grants, benefits, and contracts. The exemption of military and naval functions needs no explanation here. The exempted foreign affairs are those diplomatic functions of high importance which do not lend themselves to public procedures and with which the general public is ordinarily not directly concerned. The exemption of proprietary matters is included because in those cases the Government is in the position of an individual citizen and is concerned with its own property, funds, or contracts.

NOTICE OF RULE MAKING, SECTION 4 (A)

There are two particularly important aspects of section 4 (a), which deals with the notice of rule making. In the first place, where notice is required, it should be complete and specific as the subsection indicates on its face. In the second place, except where notice and hearing are required by some other statute, the agency by this provision is authorized to dispense with notice where it finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. This latter is not an escape clause but one which, as the committee report explains, may be made operative only where facts and interests are such that notice and proceedings are impossible or manifestly unnecessary.

PROCEDURES, SECTION 4 (B)

The second subsection of section 4 is designed to provide that, where other statutes do not require an agency hearing, the legislative functions in administrative agencies shall, so far as possible, be exercised only upon some form of public participation after notice. That is, an agency may permit parties to submit written statements, confer with industry advisory committees, hold open meetings, and the like. Whatever method is adopted, the agency must consider the data or argument so presented by interested people and incorporate a concise general statement of their basis and purpose in any rules it issues.

The effect of this provision will be to enable parties to express themselves in some informal manner prior to the issuance of rules and regulations, so that they will have been consulted before being faced with the accomplished fact of a regulation which they may not have anticipated or with reference to which they have not been consulted. This provision will make for good public relations on the part of administrative agencies. Wisely used and faithfully executed, as it must be, it should be of great aid to administrative agencies by affording them a simple statutory means of apprising the public of what they intend to do and affording the interested public a nonburdensome method of presenting its side of the case. Day by day Congress takes account of the interests and desires of the people in framing legislation; and there is no reason why administrative agencies should not do so when they exercise legislative functions which the Congress has delegated to them.

EFFECTIVE DATE OF RULES, SECTION 4 (C)

Under section 4 (c) agencies are required, in addition to the foregoing, to defer the effective date of any substantive rule for not less than 30 days except as they may specifically provide otherwise for good cause or in the case of rules recognizing exemptions or relieving restrictions, and so forth. This section places the burden upon administrative agencies to justify in law and fact the issuance of any rule effective in less than 30 days. Rules may be made effective in a legally responsible time less than 30 days because of the shown urgency of conditions coupled with demonstrated and unavoidable limitations of time. The section requires agencies to proceed with the convenience or necessity of the people

[p. 5650]

affected as the primary consideration, so that an agency may not itself be dilatory and then issue a rule requiring compliance forthwith.

PETITIONS, SECTION 4 (D)

Section 4 (d) is of the greatest importance because it is designed to afford every properly interested person statutory authority to petition for the issuance, amendment, or repeal of a rule. No agency may receive such petitions in a merely pro forma manner. Every agency possessing rule-making authority will be required to set up procedures for the receipt, consideration, and disposition of these petitions. The right of petition is written into the Constitution itself. This subsection confirms that right where Congress has delegated legislative powers to administrative agencies. As in connection with the prior provisions of section 4, this subsection should be a most useful instrument for both improving the public relations of administrative agencies and protecting the public by affording interested persons a legal and regular means of securing the issuance, change, or rescission of a rule.

[p. 5651]

HEARINGS, SECTION 7

It will be recalled that section 4—relating to rule making—and section 5—relating to the determination of particular cases—refer to situations in which Congress has by some other statute required an agency to act upon a hearing. Accordingly sections 7 and 8, which I am about to discuss, state the requisites of statutory agency hearings and decisions.

[p. 5652]

Mr. GRANGER. There are a number of us in Congress, of course, who are not lawyers. This bill I suppose is fully understood by those who are members of the legal profession. As I understood the purpose of the bill—I was somewhat confused by the gentleman's statement that it was to regulate bureaus—my impression was that it was simply a bill to make uniform rules promulgated by the bureaus and practice before the various boards and commissions of the country. Is not that generally what it is supposed to do?

Mr. GWYNNE of Iowa. No; I would not say that was all of it. It does not as a matter of fact make uniform practice before bureaus and tribunals. It requires these agencies of Government in their practice to maintain certain minimum standards. It is an attempt to bring into the practice of these bureaus and tribunals those principles of due process that we understand and that have been enforced in the courts. If I may proceed for a few minutes I believe I will make these things clear as I go along. I really wish to touch the bill a little. I will yield later if I have time.

In the matter of rule making, the bill provides, for instance, this in substance: It requires the agency to give notice of its intention to make rules and regulations. It requires the agency to allow interested parties to appear and state their views and request that certain rules and regulations be adopted. That would be much like the hearings that we now have before our committees in the House. Incidentally, that practice is now being followed by certain agencies of the Government. Then it requires that these rules or regulations which have the effect of law must be published in the Federal Register and go into effect at some future date. That is stating it very briefly but that is the substance of what is required on the important subject of rule making.

[p. 5656]

Mr. ROBSION of Kentucky. Some of the most commendable features of this bill are:

First. It defines "agency," "person," "party," "rule," "rule-making," "order" and "adjudication," "license" and "licensing," "sanction" and "relief."

Second. It provides that these orders, rules, and directives can only be adopted after reasonable notice, and, when once adopted, they must be published in the Federal Register. These records are open to the public, and they cannot be amended or changed without giving a hearing to interested parties.

Third. This bill recognizes the principles on which our three branches of government are based so that the prosecutor may not get up the evidence, prosecute the case, and, at the same time, decide the case.

Fourth. The interested parties must be given proper notice of the legal and factual issues, with due time to examine, consider, and prepare for them and the parties who are entitled to appear on their own behalf or by counsel either an attorney at law or other person who has been admitted to appear before such board or agency.

Fifth. The agency is required to afford the parties an opportunity for settlement or adjustment of the issues involved where the nature of the proceeding and the public interest permit.

Sixth. All presiding officers and deciding officers are to operate impartially. Such officer may disqualify himself and a party to the proceeding may file proper affidavit to show that the presiding officer has personal bias or is otherwise disqualified. These officers may exclude irrelevant, immaterial, or unduly repetitious evidence.

These are only a few of the many provisions of this bill that leads us to believe that it will improve the administration of justice in administrative procedure of the various agencies and further protect the constitutional rights and the interest of the American people.

[p. 5660]

Mr. KEFAUVER.

* * * * *

In this complex day when Government is interested in so many things, it is, of course, necessary to have administrative agencies which must of necessity be able to make some rules and regulations and to act in quasi-judicial positions in certain instances. Congress cannot, by the very complexity of the situation, make all of the detailed rules and regulations. But in connection with the administration of the agencies, the lawyers of America, the businessmen, and interested people have for many years been perplexed in trying to find some way to get uniformity into the making and publication of regulations and in obtaining a review procedure. Some of the agencies for many years have resisted various administrative procedure bills that have been presented on the theory that the bills would unduly hamstring them in the operation of their departments.

On the other hand, some lawyers of America and many others wanted more drastic rules for the regulation of agencies than the Congress has been willing to impose. Finally the agencies have come to realize that some orderly administration must be worked out for them and they now join in the approval of this legislation.

Various bar associations and committees that have worked on this matter have likewise joined in recommending it.

I have noticed in the debate on the bill that various Members have felt that in some instances the bill went too far, in other instances it did not go far enough; some things should be done that are not done and some things should not be done that are done. This bill will not be entirely satisfactory to everyone but it marks an excellent beginning. Only after years of practice, experience, and application can we come to see the places where it will need remedying and where it will need strengthening. I think it is going to be greatly in the public interest to have uniform administration in the various agencies of the Government.

[p. 5661]

1.15a (3)(c) May 27: Senate concurs in the House amendments, p. 5788

[No Relevant Discussion on Pertinent Section]

1.15b ADMINISTRATIVE PROCEDURE AND RULE MAKING

September 6, 1966, P.L. 89-554, §553, 80 Stat. 383

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

[p. 383]

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) A substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

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1.15b (1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 901, 89th Cong., 1st Sess. (1965)

TITLE 5, UNITED STATES CODE, "GOVERNMENT ORGANIZATION AND EMPLOYEES"

AUGUST 31, 1965.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. WILLIS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to whom was referred the bill (H.R. 10104) to enact Title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PRELIMINARY STATEMENT

Purpose.—The purpose of this bill is to restate in comprehensive form, without substantive change, the statutes in effect before

July 1, 1965, that relate to Government employees, the organization and powers of Federal agencies generally, and administrative procedure, and to enact title 5 of the United States Code. In the revised title 5, simple language has been substituted for awkward and obsolete terms, and superseded, executed, and obsolete statutes have been eliminated. This bill is a part of the program of the Committee on the Judiciary of the House of Representatives to enact into law all fifty titles of the United States Code.

[p. 1]

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

Sec.

551. Definitions.
552. Publication of information, rules, opinions, orders, and public records.
553. Rule making.
554. Adjudications.
555. Ancillary matters.
556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision.
557. Initial decisions; conclusiveness; review by agency; submissions by parties; contents of decisions; record.
558. Imposition of sanctions; determination of applications for licenses; suspension, revocation, and expiration of licenses.
559. Effect on other laws; effect of subsequent statute.

[p. 10]

SECTION 553

Derivation:	United States Code	Revised Statutes and Statutes at Large
	5 U.S.C. 1003	June 11, 1946, ch. 324, § 4, 60 Stat. 238.

In subsection (a) (1), the words "or naval" are omitted as included in "military".

In subsection (b), the word "when" is substituted for "in any situation in which".

In subsection (c), the words "for oral presentation" are substituted for "to present the same orally in any manner". The words "sections 556 and 557 of this title apply instead of this subsection" are substituted for "the requirements of sections 1006 and 1007 of this title shall apply in place of the provisions of this subsection".

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

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1.15b (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1380, 89th Cong., 2d Sess. (1966)

TITLE 5, UNITED STATES CODE, "GOVERNMENT ORGANIZATION AND EMPLOYEES"

JULY 21, 1966.—Ordered to be printed

Mr. ERVIN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to which was referred the bill (H.R. 10104), to enact title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, reports favorably thereon, with amendments, and recommends that the bill, H.R. 10104, as amended, do pass.

[p. 1]

SECTION 553

	United States Code	Revised Statutes and Statutes at Large
Derivation:	5 U.S.C. 1003	June 11, 1946, ch. 324, § 4, 60 Stat. 238.

In subsection (a) (1), the words "or naval" are omitted as included in military".

In subsection (b), the word "when" is substituted for "in any situation in which".

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Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

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1.15b(3) CONGRESSIONAL RECORD

1.15b (3) (a) VOL. 111 (1965), Sept. 7: Passed House, p. 22954

[No Relevant Discussion on Pertinent Section]

1.15b (3) (b) VOL. 112 (1966), July 25: Amended and passed Senate, p. 17010

[No Relevant Discussion on Pertinent Section]

1.15(3)(c) VOL. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077

Mr. TUCK (interrupting the reading). Mr. Speaker, I ask unanimous consent that further reading of the Senate amendments be dispensed with, and that they be printed in the RECORD.

The SPEAKER. Is there objection to the request of the gentleman from Virginia?

There was no objection.

The SPEAKER. Is there objection to the request of the gentleman from Virginia?

Mr. POFF. Mr. Speaker, reserving the right to object—and I shall not object—may I inquire of my distinguished colleague from Virginia whether any of the amendments made in the other body affect the substance of the title?

Mr. TUCK. Mr. Speaker, if the gentleman will yield, the amendments do not affect the substance of the title. They are only clerical amendments, and do not make any change in substantive law.

The original bill passed this body unanimously. It passed the Senate unanimously. The amendments were adopted by the Senate unanimously.

Mr. POFF. Mr. Speaker, I thank my colleague, and withdraw my reservation.

The SPEAKER. Is there objection to the request of the gentleman from Virginia?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

[p. 19077]

1.16 JUDICIAL REVIEW; RELIEF PENDING REVIEW; SCOPE, AS REVISED

5 U.S.C. §§705, 706(2) (A), (B), (C), (D) (1966)

[Referred to in 15 U.S.C. §1474(b)(3)(4)]

JUDICIAL REVIEW AND SCOPE

5 § 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings. Pub.L. 89–554, Sept. 6, 1966, 80 Stat. 393.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitution right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error. Pub.L 89–554, Sept. 6, 1966, 80 Stat. 393.

1.16a JUDICIAL INTERIM RELIEF AND REVIEW OF AGENCIES ACTS

June 11, 1946, P.L. 79–404, §10(d), (e), 60 Stat. 243

JUDICIAL REVIEW

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

(d) INTERIM RELIEF.—Pending judicial review any agency is authorized, where it finds that justice so requires, to postpone the effective date of any action taken by it. Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing court (including every court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

(e) SCOPE OF REVIEW.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or [p. 243] immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; (5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and due account shall be taken of the rule of prejudicial error.

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1.16a (1) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 752, 79th Cong., 1st Sess. (1945)

ADMINISTRATIVE PROCEDURE ACT

NOVEMBER 19 (legislative day, OCTOBER 29), 1945.—Ordered to be printed

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Mr. MCCARRAN, from the Committee on the Judiciary,
submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7), to improve the administration of justice by prescribing fair administrative procedure, having considered the same, reports favorably thereon, with an amendment, and recommend that the bill do pass, as amended.

There is a widespread demand for legislation to settle and regulate the field of Federal administrative law and procedure. The subject is not expressly mentioned in the Constitution, and there is no recognizable body of such law, as there is for the courts in the Judicial Code. There are no clearly recognized legal guides for either the public or the administrators. Even the ordinary operations of administrative agencies are often difficult to know. The Committee on the Judiciary is convinced that, at least in essentials, there should be some simple and standard plan of administrative procedure.

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III. STRUCTURE OF THE BILL

The bill, as reported, is not a specification of the details of administrative procedure, nor is it a codification of administrative law. Instead, out of long consideration and in the light of the studies heretofore mentioned, there has been framed an outline of minimum basic essentials. Figure 2 on page 9 diagrams the bill.

The bill is designed to afford parties affected by administrative powers a means of knowing what their rights are and how they may be protected. By the same token, administrators are provided with a simple course to follow in making administrative determinations. The jurisdiction of the courts is clearly stated. The bill thus provides for public information, administrative operation, and judicial review.

SUBSTANCE OF THE BILL.—What the bill does in substance may be summarized under four headings:

> 1. It provides that agencies must issue as rules certain specified information as to their organization and procedure, and also make available other materials of administrative law (sec. 3).
> 2. It states the essentials of the several forms of administrative proceedings (secs. 4, 5, and 6) and the limitations on administrative powers (sec. 9).
> 3. It provides in more detail the requirements for administrative hearings and decisions in cases in which statutes require such hearings (sec. 7 and 8).
> 4. It sets forth a simplified statement of judicial review designed to afford a remedy for every legal wrong (sec. 10).

The first of these is basic, because it requires agencies to take the initiative in informing the public. In stating the essentials of the different forms of administrative proceedings, it carefully distinguishes between the so-called legislative functions of administrative agencies (where they issue general regulations) and their judicial functions (in which they determine rights or liabilities in particular cases).

The bill provides quite different procedures for the "legislative" and "judicial" functions of administrative agencies. In the "rule making" (that is, "legislative") function it provides that, with certain exceptions, agencies must publish notice and at least permit interested parties to submit their views in writing for agency consideration before issuing general regulations (sec. 4). No hearings are required by the bill unless statutes already do so in a particular case. Similarly, in "adjudications" (that is, the "judicial" function) no agency hearings are required unless statutes already do so, but in the latter case the mode of hearing and decision is prescribed [p. 7] (sec. 5). Where existing statutes require that either general regulations (called "rules" in the bill) or particularized adjudications (called "orders" in the bill) be made after agency hearing or opportunity for such hearing, then section 7 spells out the minimum requirements for such hearings, section 8 states how decisions shall be made thereafter, and section 11 provides for examiners to preside at hearings and make or participate in decisions.

While the administrative power and procedure provisions of sections 4 through 9 are law apart from court review, the provisions for judicial review provide parties with a method of enforcing their rights in a proper case (sec. 10). However, it is expressly provided that the judicial review provisions are not operative where statutes otherwise preclude judicial review or where agency action is by law committed to agency discretion.

KINDS OF PROVISIONS.—The bill may be said to be composed of five types of provisions:

1. Those which are largely formal such as the sections setting forth the title (sec. 1), definitions (sec. 2), and rules of construction (sec. 12).
2. Those which require agencies to publish or make available information on administrative law and procedure (sec. 3).
3. Those which provide for different kinds of procedures such as rule making (sec. 4), adjudications (sec. 5), and miscellaneous matters (sec. 6) as well as for limitations upon sanctions and powers (sec. 9).
4. Those which provide more of the detail for hearings (sec. 7) and decisions (sec. 8) as well as for examiners (sec. 11).
5. Those which provide for judicial review (sec. 10).

The bill is so drafted that its several sections and subordinate provisions are closely knit. The substantive provisions of the bill should be read apart from the purely formal provisions and minor functional distinctions. The definitions in section 2 are important, but they do not indicate the scope of the bill since the subsequent provisions make many functional distinctions and exceptions. The public information provisions of section 3 are of the broadest application because, while some functions and some operations may not lend themselves to formal procedure, all administrative operations should as a matter of policy be disclosed to the public except as secrecy may obviously be required or only internal agency "housekeeping" arrangements may be involved. Sections 4 and 5 prescribe the basic requirements for the making of rules and the adjudication of particular cases. In each case, where other statutes require opportunity for an agency hearing, sections 7 and 8 set forth the minimum requirements for such hearings and the agency decisions thereafter while section 11 provides for the appointment and tenure of examiners who may participate. Section 6 prescribes the rights of private parties in a number of miscellaneous respects which may be incidental to rule making, adjudication, or the exercise of any other agency authority. Section 9 limits sanctions, and section 10 provides for judicial review.

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SEC. 10. JUDICIAL REVIEW.—*Section 10 on judicial review does not apply in any situation so far as there are involved matters with respect to which statutes preclude judicial review or agency action is by law committed to agency discretion.*

Very rarely do statutes withhold judicial review. It has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board.

The basic exception of matters committed to agency discretion would apply even if not stated at the outset. If, for example, statutes are drawn in such broad terms that in a given case there is no law to apply, courts of course have no statutory question to review. That situation cannot be remedied by an administrative procedure act but must be treated by the revision of statutes conferring administrative powers. However, where statutory standards, definitions, or other grants of power deny or require action in given situations or confine an agency within limits as required by the Constitution, then the determination of the facts does not lie in agency discretion but must be supported by either the administrative or judicial record.

(*a*) RIGHT OF REVIEW.—*Any person suffering legal wrong because of any agency action, or adversely affected within the meaning of any statute, is entitled to judicial review.*

This subsection confers a right of review upon any person adversely affected in fact by agency action or aggrieved within the meaning of any statute. The phrase "legal wrong" means such a wrong as is specified in subsection (e) of this section. It means that something more than mere adverse personal effect must be shown—that is, that the adverse effect must be an illegal effect. The law so made relevant is not just constitutional law but any and all applicable law.

[p. 26]

* * * * * * *

JUDICIAL REVIEW

SEC. *10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—*

(a) Right of review.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) Form and venue of action.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) Reviewable acts.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action shall be final whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule) for an appeal to superior agency authority.

(d) Interim relief.—Pending judicial review any agency is authorized where it finds that justice so requires, to postpone the effective date of any action taken by it. Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing court (including every court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

(e) Scope of review.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; (5) unsupported by substantial

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evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by the parties, and due account shall be taken of the rule of prejudicial error.

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Section 10 (d): The first sentence states existing law. The second sentence may be said to change existing law only to the extent that the language of the opinion in *Scripps-Howard Radio, Inc.* v. *Federal Communications Commission* (316 U. S. 4, 14) may be interpreted to deny to reviewing courts the power to permit an applicant for a renewal of a license to continue to operate as if the original license had not expired, pending conclusion of the judicial review proceedings. In any event, the court must find, of course, that granting of interim relief is necessary to prevent irreparable injury.

Section 10 (e): This declares the existing law concerning the scope of judicial review. The power of the court to direct or compel agency action unlawfully withheld or unreasonably delayed is not intended to confer any nonjudicial function or to narrow the principle of continuous administrative control enunciated by the Supreme Court in *Federal Communications Commission* v. *Pottsville Broadcasting Co.* (309 U.S. 134). Clause (5) is intended to embody the law as declared, for example, in *Consolidated Edison Co.* v. *National Labor Relations Board* (305 U.S. 197). There the Chief Justice said: "Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion (p. 229) * * * assurance of a desirable flexibility in administrative procedure does not go so far as to justify orders without a basis in evidence having rational probative force" (p. 230).

The last sentence of this section makes it clear that not every failure to observe the requirements of this statute or of the law is ipso facto fatal to the validity of an order. The statute adopts the rule now well established as a [p. 44] matter of common law in all jurisdictions that error is not fatal unless prejudicial.

Section 11: This section provides for the appointment, compensation, and tenure of examiners who will preside over hearings and render decisions pursuant to sections 7 and 8. The section provides that appointments shall be made "subject to the civil service and other laws to the extent not inconsistent with this act." Appointments are to be made by the respective employing agencies of personnel determined by the Civil Service Commission to be qualified and competent examiners. The examiners appointed are to serve only as examiners, except that, in particular instances (especially where the volume of hearings under a given statute or in a given agency is not very great), examiners may be assigned additional duties which are not inconsistent with or which do not interfere with their duties as examiners. To insure equality of participation among examiners in the hearing and decision of cases, the agencies are required to use them in rotation so far as may be practicable.

Examiners are subject to removal only for good cause "established and determined" by the Commission. The Commission must afford the examiner a hearing, if requested, and must rest its decision solely upon the basis of the record of such hearing. It should be noted that the hearing and the decision are to be conducted and made pursuant to the provisions of sections 7 and 8.

Section 11 provides further that the Commission shall prescribe the compensation of examiners, in accordance with the compensation schedules provided in the Classification Act, except that the efficiency rating system set forth in that act shall not be applicable to examiners.

Section 12: The first sentence of section 12 is intended simply to indicate that the act will be interpreted as supplementing constitutional and legal requirements imposed by existing law.

The section further provides that "no subsequent legislation shall be held to supersede or modify the provisions of this act except to the extent that such legislation shall do so expressly." It is recognized that no congressional legislation can bind subsequent sessions of the Congress. The present act can be repealed in whole or in part at any time after its passage. However, the act is intended to express general standards of wide applicability. It is believed that the courts should as a rule of construction interpret the act as applicable on a broad basis, unless some subsequent act clearly provides to the contrary.

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1.16a(2) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 1980, 79th Cong., 2d Sess. (1946)

ADMINISTRATIVE PROCEDURE ACT

MAY 3, 1946.—Committed to the Committee of the Whole House on the State of the Union and Ordered to be printed

Mr. WALTER, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 7]

The Committee on the Judiciary, to whom was referred the bill (S. 7) to improve the administration of justice by prescribing fair administrative procedure, having considered the same, report the bill favorably to the House, with an amendment, with the recommendation that, as amended, the bill do pass.

The committee amendment is as follows:

Strike out all of the bill after the enacting clause and insert in lieu thereof the following:

TITLE

SECTION 1. This Act may be cited as the "Administrative Procedure Act".

* * * * * * *

[p. 1]

of this Act or other proceedings required by law and shall make its decision. Except in cases of willfulness or those in which public health interest, or safety requires otherwise, no withdrawal, suspension, revocation, or annulment of any license shall be lawful unless prior to the institution of agency proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee by the agency in writing and the licensee shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements. In any case in which the licensee has in accordance with agency rules made timely and sufficient application for a renewal or a new license, no license with reference to any activity of a continuing nature shall expire until such application shall have been finally determined by the agency.

JUDICIAL REVIEW

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

(d) INTERIM RELIEF.—Pending judicial review any agency is authorized, where it finds that justice so requires, to postpone the effective date of any action taken by it. Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing court (including every court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

(c) SCOPE OF REVIEW.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory rights; (4) without observance of procedure required by law; (5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and the account shall be taken of the rate of judicial error.

EXAMINEES

SEC. 11. Subject to the civil-service and other laws to the extent not inconsistent with this Act, there shall be appointed by and for each agency as many qualified and competent examiners as may be necessary for proceedings pertinent to sections 7 and 8 who shall be assigned to cases in rotation so far as practicable.

SECTION 10 (D). TEMPORARY RELIEF PENDING FULL REVIEW

Pending judicial review any agency may postpone the effective date of its action. Upon conditions and as may be necessary to prevent irreparable injury, any reviewing court may postpone the effective date of any agency action or preserve the status quo pending conclusion of review proceedings.

This section permits either agencies or courts, if the proper showing be made, to maintain the status quo. The section is in effect a statutory extension of rights pending judicial review, although the reviewing court must order the extension; or, to put the situation another way, status authorizing agency action are to be construed to extend rights pending judicial review and the exclusiveness of the administrative remedy is diminished so far as this section operates. While the section would not permit a court to grant an initial license, it provides intermediate judicial relief for every other situation in order to make judicial review effective. The authority granted is equitable and should be used by both agencies and courts to prevent irreparable injury or afford parties an adequate judicial remedy. Such relief would normally, if not always, be limited to the parties complainant and may be withheld in the absence of a substantial question for review. In determining whether agency action should be postponed, the court should take into account that persons other than parties [p. 43] may be adversely affected by such postponement and in such cases the party seeking postponement may be required to furnish security to protect such other persons from loss resulting from postponement.

SECTION 10 (E). SCOPE OF COURT REVIEW

Reviewing courts are required to decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of any agency action. They must (A) compel action unlawfully withheld or unreasonably delayed and (B) hold unlawful any action, findings, or conclusions found to be (1) arbitrary or an abuse of discretion, (2) contrary to the Constitution, (3) contrary to statutes or statutory right, (4) without observance of procedure required by law, (5) unsupported by substantial evidence in any case reviewed upon the record of an agency hearing provided by statute, or (6) unwarranted by the facts so far as the latter are subject to trial de novo. In making these determinations the court is to consider the whole record or such parts as any party may cite, and due account must be taken of the rule of prejudicial error.

This section provides that questions of law are for courts rather than agencies to decide in the last analysis and it also lists the several categories of questions of law. Under it courts are required to determine the application or threatened application or questions respecting the validity or terms of any agency action notwithstanding the form of the proceeding or whether brought by private parties for review or by public officers or others for enforcement. It expressly recognizes the right of properly interested parties to compel agencies to act where they improvidently refuse to act. "Finding" and "conclusion" also mean failure to find or conclude as the law and the record may require. "Accordance with law" requires, among other things, a judicial determination of the authority or propriety of interpretative rules and statements of policy. "Short of statutory right" means that agencies are not authorized to give partial relief where a party demonstrates his right to the whole. Authorized relief must be granted by an agency to the full extent that entitlement is shown.

"Without observance of procedure required by law" means not only the procedures required and procedural rights conferred by this bill but any other procedures or procedural rights the law may require. Except in a few respects, this is not a measure conferring administrative powers but is one laying down definitions and stating limitations. These definitions and limitations must, to be sure, be interpreted and applied by agencies affected by them in the first instance. But the enforcement of the bill, by the independent judicial interpretation and application of its terms, is a function which is clearly conferred upon the courts in the final analysis. It will thus be the duty of reviewing courts to prevent avoidance of the requirements of the bill by any manner or form of indirection, and to determine the meaning of the words and phrases used. For example, in several provisions the expression "good cause" is used. The cause so specified must be interpreted by the context of the provision in which it is found and the purpose of the entire section and bill. Cause found must be real and demonstrable. If the agency is proceeding upon a statutory hearing and record, the cause will appear there; otherwise it must be such that the agency may show the facts and considera-

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tions warranting the finding in any proceeding in which the finding is challenged. The same would be true in the case of findings other than of good cause, required in the bill. As has been said, these findings must in the first instance be made by the agency concerned but, in the final analysis, their propriety in law and on the facts must be sustainable upon inquiry by a reviewing court.

"Substantial evidence" means evidence which on the whole record is clearly substantial, plainly sufficient to support a finding or conclusion under the requirements of section 7 (c), and material to the issues. It is exceedingly important. Difficulty has come about by the practice of agencies and courts to rely upon something less—suspicion, surmise, implications, or plainly incredible evidence. Although the agency must do so in the first instance, under this bill it will be the duty of the courts to determine in the final analysis and in the exercise of their independent judgment whether on the whole of the proofs brought to their attention the evidence in a given instance is sufficiently substantial to support a finding, conclusion, or other agency action or inaction. In reviewing a case under this fifth category the court must base its judgment upon its own review of the entire record or so much thereof as may be cited by any party.

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JUDICIAL REVIEW

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement

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except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedure, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action *otherwise final* shall be final *for the purposes of this subsection* whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule *and provides that the action meanwhile shall be inoperative* for an appeal to superior agency authority.[21]

(d) INTERIM RELIEF.—Pending judicial review any agency is authorized, where it finds that justice so requires, to postpone the effective date of any action taken by it. Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing court (including every court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

(e) SCOPE OF REVIEW.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, *an abuse of discretion*,[22] or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; (5) unsupported by substantial evidence in any case subject to the requirements of section 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by [the parties]*any party*,[23] and due account shall be taken of the rule of prejudicial error.

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[21] The change is made to clarify the provision by making specifically the language of the bill the explanation given in the Senate Committee report (p. 27). It should be noted that section 8 (a) permits agencies to provide by rule for appeals to them from initial decisions of examiners. That provision, as well as this provision of section 10 (c), would authorize an agency to adopt rules requiring a party to take a timely appeal to the agency before resorting to the courts. A party cannot wilfully fail to exhaust his administrative remedies and then, after the agency action has become operative, either secure a suspension of the agency action by a belated appeal to the agency, or resort to court without having given the agency an opportunity to determine the questions raised. If he so fails he is precluded from judicial review by the application of the time-honored doctrine of exhaustion of administrative remedies. This is not to say that after the right to an administrative appeal has lapsed an agency may not, on proper application, either reconsider an adjudication or receive proposals for the modification of a rule, with or without suspending the operation of the agency action involved.

[22] The change is designed to make it clear that S. 7 preserves judicial review of abuses of discretion.

[23] This change is to conform the language with the similar provision in sec. 7(c).

1.16a(3) CONGRESSIONAL RECORD, VOL. 92 (1946)

1.16a(3)(a) March 12: Amended and passed Senate, pp. 2151, 2153, 2158, 2166

Mr. McCARRAN.

* * * * *

Five types of provisions compose this bill. They are:

First. Provisions which are largely formal, such as the sections setting forth the title, definitions, and rules of construction.

Second. Provisions which require agencies to publish or make available information on administrative law and procedure.

Third. Provisions for different kinds of procedures such as rule-making, adjudications, and miscellaneous matters, as well as for limitations upon sanctions and powers.

Fourth. Provisions concerning the detail for hearings and decisions as well as for examiners.

Fifth. Provisions for judicial review.

I desire to emphasize the fifth type of provisions, namely, provisions for judicial review, because it is something in which the American public has been and is much concerned, harkening back, if we may, to the Constitution of the United States, which sets up the judicial branch of the Government for the redress of human wrongs and for the enforcement of human rights.

[p. 2151]

Mr. McCARRAN. I have not in mind the language to which the able Senator refers, but the language as I heard him read it is rather common language addressing itself to that subject. My conception of the term "legal wrong" is set forth in the committee report on page 26:

> The phrase "legal wrong" means such a wrong as is specified in subsection (e) of this section. It means that something more than mere adverse personal effect must be shown—that is, that the adverse effect must be an illegal effect. The law so made relevant is not just constitutional law, but any and all applicable law.

Let me read further in connection with the construction which I place on the term:

> Reviewing courts are required to decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of any agency action. They must (A) compel action unlawfully withheld or unreasonably delayed and (B) hold unlawful any action, findings, or conclusions found to be (1) arbitrary, (2) contrary to the Constitution (3) contrary to statutes or short of statutory right, (4) without observance of procedure required by law, (5) unsupported by substantial evidence upon the administrative record where the agency is authorized by statute to hold hearings subject to sections 7 and 8, or (6) unwarranted by the facts so far as the latter are subject to trial de novo.

I have tried to anticipate the question which the able Senator has propounded to me. I am glad that he asked the question. I have tried to define the term, because I thought it might be well to have it defined in the RECORD.

Mr. AUSTIN. Mr. President, will the Senator further yield?

Mr. McCARRAN. I yield.

Mr. AUSTIN. I see the application of what the distinguished Senator has just stated to the following part of the clause in section 10 (a) namely, "or adversely affected or aggrieved by such action within the meaning of any relevant statute." That is another category of men and women who are entitled to review. But my question was limited to the category described as "any person suffering legal wrong because of any agency action." On this point I should like to read further from the definition of "wrong," because this is a new use of the word. If the author of the bill intends by the use of the term "legal wrong" what is here set forth, I should like to have it in the RECORD, because it would save a great deal of controversy. May I take the time of the Senator to read further from the definition of "wrong" in Bouvier's Law Dictionary?

Mr. McCARRAN. Yes; I should like to have the Senator read it.

Mr. AUSTIN. The definition is as follows:

> Wrong. An injury; a tort; a violation of right.
>
> In its broad sense, it includes every injury to another, independent of the motive causing the injury (*Union Pac. Ry. Co.* v. *Henry* (36 Kan. 570. 14 Pac. 1)).
>
> A wrong is an invasion of right to the damage of the party who suffers it. It consists in the injury done, and not commonly in the purpose or mental or physical capacity of the person or agent doing it. It may or may not have been done with bad motive; the question of motive is usually a question of aggravation only (*Williams* v. *Hays* (143 N. Y. 417, 38 N.E. 449, 26 L. R. A. 153, 42 Am. St. Rep. 743)).
>
> In its most usual sense, wrong signifies an injury committed to the person or property of another, or to his relative rights unconnected with contract; and these wrongs are committed with or without force. But in a more extended signification, wrong includes the violation of a contract; a failure by a man to perform his undertaking or promise is a wrong or injury to him to whom it was made (3 Bla. Com. 158).
>
> A public wrong is an act which is injurious to the public generally, commonly known by the name of crime, misdemeanor, or offense; and it is punishable in various ways, such as indictments, summary proceedings and, upon conviction, by death, imprisonment, fine, etc.
>
> Private wrongs, which are injuries to individuals, unaffecting the public; these are redressed by actions for damages, etc. See Remedies; Tort.
>
> For a classification of wrongs, see Holland, Jurisprudence 270.

The combination of words used here is very significant. The adjective "legal" is a limiting adjective; and, as it has been applied in jurisprudence to "injury," it is defined as follows in Words and Phrases, fourth series, second volume, page 548:

> "Legal injury" must be violation of some legal right and is distinct from "damage," which is harm, or loss, sustained by injury (*Combs* v. *Hargis Bank & Trust Co.* (27 S. W. (2d) 955, 956, 234 Ky. 202)).

For the sake of the future of those practicing under this estimable bill, I think it would be well to have the RECORD show whether the distinguished author of the bill regards the category of persons entitled to review which is here described, that is, "any person suffering legal wrong," as any person who has suffered in the manner described in the quotation from Bouvier's Law Dictionary.

Mr. McCARRAN. Taking Bouvier and Words and Phrases combined, and taking the decisions of the courts of last resort, to whose language we have access, I should answer the Senator "yes." That is, I take into consideration all the definitions which apply to define that term, and I respectfully refer to the committee report, which I read a moment ago. It means that something more than mere adverse personal effect must be shown; that is, that the adverse effect must be an illegal effect. So, to Bouvier, to Words and Phrases, and to the decisions to which the able Senator refers, I also add the expression contained in the committee report.

Mr. AUSTIN. I thank the Senator.

Mr. McCARRAN. Let me go a little further, because I am very grateful to the Senator for bringing up this question. We asked the Attorney General and the Department of Justice to comment on this bill. I now read to the Senate the Attorney General's comment:

> Section 10 (a): Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review of such action. This reflects existing law. In *Alabama Power Co.* v. *Ickes* (302 U. S. 404), the Supreme Court stated the rule concerning persons entitled to judicial review. Other cases having an important bearing on this subject are: *Massachusetts* v. *Mellon* (262 U.S. 447), *The Chicago Junction Case* (264 U. S. 258), *Sprunt & Son* v. *United States* (281 U. S. 249), and *Perkins* v. *Lukens Steel Co.* (310 U. S. 113). An important decision interpreting the meaning of the terms "aggrieved" and "adversely affected" is *Federal Communications Commission* v. *Sanders Bros. Radio Station* (309 U.S. 470).

Mr. President, I have referred the Senator to that expression coming from the Attorney General, in connection with this bill, to indicate to him and to the Senate the meticulous study which we have tried to give to this bill, so that we may construe the terms in such a way that there may be no divergence of views when we get through.

I realize that the layman says this is an intricate bill. In a way it is, and yet in a way it simplifies itself in practice.

[p. 2153]

Mr. McCARRAN.

* * * * *

Section 10 is the section which relates to judicial review. This section does not apply in any situation so far as there are involved matters with respect to which existing statutes preclude judicial review, or with respect to which agency action is by law committed to agency discretion.

Subsection (a) of section 10 provides that any person suffering legal wrong because of any agency action, or adversely affected within the meaning of any statute, is entitled to judicial review.

Subsection (b) of section 10 concerns the form and venue of action. It provides that the technical form of proceeding for judicial review is any special proceeding provided by statute, or, in the absence or inadequacy thereof, any relevant form of legal action, such as those for declaratory judgments or injunctions, in any court of competent jurisdiction. Furthermore, under this subsection, agency action is also made subject to judicial review in any civil or criminal proceeding for enforcement, except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

Subsection (c) of section 10 concerns reviewable acts of agencies. This subsection provides that agency action made reviewable specially by statute, or final agency action for which there is no other adequate judicial remedy, is subject to judicial review. In addition, preliminary or procedural matters not directly subject to review are made reviewable upon the review of final actions. Except as statutes may expressly require otherwise, agency action is final regardless of whether there has been presented or determined any application for a declaratory order, for any form of reconsideration, or unless the agency otherwise requires by rule, for an appeal to superior agency authority.

Subsection (d) of section 10 concerns interim relief. It provides that pending judicial review, any agency may postpone the effective date of its action. Upon conditions, and as may be necessary to prevent irreparable injury, any reviewing court may postpone the effective date of any agency action, or preserve the status quo pending conclusion of review proceedings.

Subsection (e) of section 10 concerns the scope of review. Under this subsection, reviewing courts are required to decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of any agency action. Such courts are required to compel action shown to be unlawfully withheld or unreasonably delayed. They are required to hold unlawful any action, findings, or conclusions found to be either arbitrary or contrary to the Constitution or contrary to statutes or short of statutory right or without observance of procedure required by law or unsupported by substantial evidence upon the administrative record, where the agency is authorized by statute to hold hearings subject to sections 7 and 8, or unwarranted by the facts insofar as the latter are subject to trial de novo. In making these determinations the court is to consider the whole record or such parts as the parties may cite, and due account must be taken of the rule of prejudicial error.

[p. 2158]

JUDICIAL REVIEW

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) Right of review: Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) Form and venue of action: The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) Reviewable acts: Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action shall be final whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule) for an appeal to superior agency authority.

(d) Interim relief: Pending judicial review any agency is authorized, where it finds that justice so requires, to postpone the effective date of any action taken by it. Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing court (including every court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings.

(e) Scope of review: So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, findings and conclusions found to be (1) arbitrary, capricious, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law: (5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by the parties, and due account shall be taken of the rule of prejudicial error.

[p. 2166]

1.16a(3)(b) May 24: Debated, amended and passed House, pp. 5454–5457, 5660, 5666

Mr. SABATH.

* * * * *

JUDICIAL REVIEW, SECTION 10

Section 10 is a comprehensive statement of the right, mechanics, and scope of judicial review. It requires an effective, just, and complete determination of every case and every relevant issue. It is a means of enforcing all forms of law and all types of legal limitations. Every form of statutory right or limitation would thus be subject to judicial review under the bill. It would not be limited to constitutional rights or limitations alone—See *Perkins* v. *Lukens Steel Co.* (310 U.S. 113).

Two general exceptions are made in the introductory clause of section 10. The first exempts all matters so far as statutes preclude judicial review. Congress has rarely done so. Legislative intent to forbid judicial review must be, if not specific and in terms at least clear, convincing, and unmistakable under this bill. The mere fact that Congress has not expressly provided for judicial review would be completely immaterial—see *Stark v. Wickard* (321 U.S. 288 at p. 317).

The second general limitation on the section is that there are exempted matters to the extent that they are by law committed to the absolute discretion of administrative agencies. There have been much misunderstanding and confusion of terms respecting the discretion of agencies. They do not have authority in any case to act blindly or arbitrarily. They may not willfully act or refuse to act. Although like trial courts they may determine facts in the first instance and determine conflicting evidence, they cannot act in disregard of or contrary to the evidence or without evidence. They may not take affirmative or negative action without the factual basis required by the laws under which they are proceeding. Of course, they may not proceed in disregard of the Constitution, statutes, or other limitations recognized by law.

RIGHT OF REVIEW, SECTION 10 (A)

The first subsection of section 10 provides that any person suffering legal wrong because of any agency action, or adversely affected within the meaning of any statute, is entitled to judicial review. Legal wrong means action of inaction in violation of the law or the facts. The categories of questions of legal wrong are set forth later as subsection (e) of section 10.

FORMS OF REVIEW ACTIONS, SECTION 10 (B)

Under this bill the technical form of proceeding for judicial review is, first, any special proceeding which Congress has provided or, in the absence or inadequacy thereof, any relevant form of action such as those for declaratory judgments or injunctions in any court of competent jurisdiction. In addition, any agency action is also subject to judicial review in any civil or criminal enforcement proceeding except to the extent that prior, adequate, and exclusive opportunity for such review is otherwise provided by law.

These provisions summarize the situation as it is now generally understood. The section does not disturb special proceedings which Congress has provided, nor does it disturb the venue arrangements under existing law. It does, however, constitute a statutory adoption of traditional forms of action in cases where Congress has made no contrary provision for judicial review.

REVIEWABLE ACTS, SECTION 10 (C)

In any proceeding for judicial review, the parties who seek it must specify what it is they wish reviewed and what it is they claim to be reviewable. Accordingly, secton 10 (c) provides that specific acts which are either expressly made reviewable by legislation or for which there is no other adequate judicial remedy are subject to review under section 10 of this bill. Preliminary or procedural matters not so reviewable may be reviewed in connection with final actions. An act is final whether or not there has been presented or determined an application for any form of reconsideration, unless statutes otherwise expressly require.

The provisions of this section are technical but involve no departure from the usual and well understood rules of procedure in this field.

TEMPORARY RELIEF, SECTION 10 (D)

Of importance in the field of judicial review is the authority of courts to grant temporary relief pending final decision of the merits of a judicial-review action. Accordingly section 10 (d) provides that any agency may itself postpone the effective date of its action pending judicial review or, upon conditions and as may be necessary to prevent irreparable injury, reviewing courts may postpone the effective date of contested action or preserve the status quo pending conclusion of judicial-review proceedings.

The section is a definite statutory statement and extension of rights pending judicial review. It thus, so far as necessary, amends statutes conferring exclusive authority upon administrative agencies to take or withhold action. Its operation will involve no radical departures from what has generally been regarded as an essential and inherent right of the courts; but, however that may be, this provision confers full authority to courts to protect the review process and purpose otherwise expressed in section 10.

SCOPE OF REVIEW, SECTION 10 (E)

The final subsection of section 10 states the extent or degree of review which courts are required to afford under this bill. I have already referred to the exemption of situations in which Congress has specifically withheld review or in which action has by law been committed to the absolute discretion of administrative agencies.

Subsection (e) of section 10 requires courts to determine independently all relevant questions of law, including the interpretation of constitutional or statutory provisions and the determination of the meaning or applicability of any agency action. They must compel action unlawfully withheld or unreasonably delayed. They must hold unlawful any action, findings or conclusions which they find to be, first, arbitrary or in abuse of discretion; second, contrary to any provision of the Constitution; third, in violation of statutes or statutory rights; fourth, without observance of procedure required by law; fifth, unsupported by substantial evidence in any case reviewed upon the record of an agency hearing provided by statute; or, sixth, unwarranted by the facts so far as the latter are subject to trial de novo. In making these determinations the court is to consider the whole record or such parts as any party may cite and, where error has been fully cured prior to the effective date of agency action, the courts may apply the rule respecting nonprejudicial error.

The term "substantial evidence" as used in this bill means evidence which on the whole record as reviewed by the court and in the exercise of the independent judgment of the reviewing court is material to the issues, clearly substantial, and plainly sufficient to support a finding or conclusion affirmative or negative in form under the requirements of section 7 (c) heretofore

[p. 5654]

discussed. Under this section the function of the courts is not merely to search the record to see whether it is barren of any evidence, or lacking any vestige of reliable and probative evidence, or supports the agency action by a scintilla or by mere hearsay, rumor, suspicion, speculation, and inference—cf. *Edison Co.* v. *Labor Board* (305 U. S. 197, 229-230). Under this bill it will not be sufficient for the court to find, as the late Chief Justice Stone pointed out within the year, merely that there is some "tenuous support of evidence"—*Bridges* v. *Wixon* (326 U. S. at 178). Nor may the bill be construed as permitting courts to accept the judgments of agencies upon unbelievable or incredible evidence.

Where there is no statutory administrative hearing to which review is confined, the facts pertinent to any relevant question of law must, of course, be tried and determined de novo by the reviewing court.

Whether a court is proceeding upon an administrative or a judicial record, the requirement of review upon the whole record means that courts may not look only to the case presented by one of the parties but must decide upon all of the proofs submitted.

[p. 5655]

Mr. GWYNNE of Iowa.

* * * * *

The only other and remaining feature I would like to mention has to do with appeals, then I shall be glad to yield. The great difficulty with our present setup is that many of these agencies are not subject to court review and many of them even if we pass this bill will still not be subject to court review. This bill does not give a court review in any case where review is now precluded by statute. It simply clarifies and expands in some particulars the authority of the court in reviewing cases in which court review is not precluded by law. In general they can reverse or modify the judgment on these grounds:

First. If the finding is contrary to some provision of the Constitution;

Second. If the tribunal or agency has failed to follow the procedure provided by law;

Third. If the decision is arbitrary or capricious; and

Finally, and very important, if the finding of the agency is not supported by substantial evidence.

[p. 5656]

Mr. SPRINGER.

* * * * *

The gentleman from Iowa [Mr. GWYNNE] has gone rather carefully over the provisions of the bill. I desire to call attention to only one, and that is the fourth provision, relating to the question of reviewable acts, the review of the proceedings by the judiciary, and the scope of the review. Under the present procedure, in many cases where there is any evidence, even a scintilla of evidence, decisions have been rendered and predicated on that character of evidence before the hearing tribunal.

Mr. HANCOCK. Even though contrary to the preponderance of the evidence.

Mr. SPRINGER. Yes, as the distinguished gentleman from New York says, that has been done in many cases even though it is contrary to the preponderance of the evidence introduced at the hearing.

May I say further on this particular point that in many instances the evidence upon which a decision has been predicated has not been competent evidence.

The bill pending before this committee, and which I hope will be passed without a dissenting vote, provides for judicial review in certain instances, and it takes up the scope of the review. It is to that particular feature that I desire to address the few comments I have to make upon this measure.

Page 39 of the bill provides that under this law the reviewing courts "shall compel agency action unlawfully withheld or unreasonably delayed."

In many of those cases there has been a withholding or a long delay, and that particular feature is intended to hasten action on the part of these agencies. I feel confident each Member will approve that provision in this bill.

The second provision, to which I now refer, provides "and hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

To my mind, that is a most potent statement and is a fair and equitable provision of the bill.

Mr. SCRIVNER. Mr. Chairman, will the gentleman yield?

Mr. SPRINGER. I am happy to yield to my friend from Kansas.

Mr. SCRIVNER. Does the gentleman feel that that would correct the evils that might exist where a regulation was contrary to the intent, spirit, or purpose of the act?

Mr. SPRINGER. I think, unquestionably, it would. The gentleman is precisely correct. That is the purpose and that is the intention of that provision which has been written into this bill. In those cases where these decisions are found to be arbitrary, where the decision is found to be capricious or an abuse of discretion or otherwise not in accordance with the law, the decision can be set aside. That is certainly fair, that is certainly equitable, and that is certainly based upon a sound philosophy.

The next provision under the scope of review to which I desire to call the attention of the Members is that any decision can be set aside which is contrary to constitutional right, power, privilege, or immunity. There is no one in the world who could object to a provision of that kind because that is based upon the sound philosophy of the law.

The following provision in the scope of review that I desire to call to the attention of the Members is that in cases "where the decision is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," such decision can be set aside. In other words, where the person who has been tried has had taken away from him the legal rights to which he is entitled; or the limitation to which he is entitled under the provisions of the law have been reduced, then that character of decision under the scope provided in this bill can be set aside.

Fourth. "Without observance of procedure required by law." That is a potent and powerful reason. Decisions thus can be set aside where there is no observance of the legal procedure on the part of the hearing administrator or agent. When that authority has been taken into his hands and he has failed to observe the legal requirements and procedures, then such a decision, predicated upon that theory, can be set aside.

Fifth. "A decision which is unsupported by substantial evidence" can be set aside. I mentioned just a little while ago that many cases in which decisions have been rendered upon a mere scintilla of evidence, and not on the weight of the evidence, have been discovered. In many instances the decisions have been based upon evidence which is not competent. But under the provisions of this bill it is required that all such decisions shall be based upon and predicated upon substantial evidence. That is the only fair basis upon which decisions of this character should be made by either a court or any agency assuming the authority to hear and determine cases.

The sixth provision applies to decisions unwarranted by the facts to the extent that the facts are subject to a trial de novo by the reviewing court. It is my judgment that under the scope of review set forth in the pending bill it wll give every person the opportunity and right to have a fair, just, and impartial trial in the judicial proceeding, and a complete review of the case which has been conducted against him. I hope this bill is passed without any objection. This worth-while legislation has been too long delayed already, and it is my hope that it will be passed in the House, fully approved by the other body, and promptly signed by the President.

[p. 5657]

Mr. RUSSELL. Mr. Chairman, at the outset I must agree that this bill in its entirety will be a valuable asset to the people of America if it is passed. In the main, it seeks to give the courts a little more function with regard to administrative agencies' rulings, decrees, orders, and judgments. In that respect I am in full accord with the terms of the bill.

Being a member of the lawyers' profession, I have always looked upon the functions of our courts and the jurisprudence of our country in general with jealousy and zealousness. I have always been able to speak with pride of the jurisprudence of the American Government because of the fundamental principles underlying the rules by which the courts, both trial and appellate, are guided. Perhaps some of you do not know it, but as far as I know, without a single exception each general principle of the rules of evidence that have been adopted by the courts is based upon some Biblical quotation. Every rule is taken from the Bible, when you analyze it and run it back to its source. This fact alone should make the American people proud of American jurisprudence. There is one thing I am somewhat apprehensive about in regard to this bill. It is for that reason I take the floor for these few minutes. If you will turn with me to page 38 to subsection (c) of section 10, I want to read the first part of that paragraph to you. It is as follows:

> Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review.

That is fine. That is excellent. That is what the American people have been clamoring for for the last few years. The Congress has been clamoring for it too. The paragraph reads further:

> Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action.

Now, that is fine, But here is the clause or phrase that I am afraid of:

> Except as otherwise expressly required by statute—

I am afraid of that provision. I am not in a position, because I did not know the bill was up for consideration, and I happened into the Chamber and heard this discussion, to answer directly the way in which I think this would preserve the dictatorial powers of that agency or that authorization by law. The law, of course, is what the Congress makes. There are some laws which I am not able to point out to you right now which make it possible for an agency to pass upon a question presented to them on the basis of the slightest evidence, whether it be relevant or irrelevant, whether it be material or immaterial, and whether it be prejudicial or not prejudicial.

The CHAIRMAN. The time of the gentleman from Texas has expired.

Mr. SUMNERS of Texas. Mr. Chairman, I yield three additional minutes to the gentleman.

Mr. SPRINGER. Mr. Chairman, I yield one additional minute to the gentleman.

Mr. RUSSELL. When an agency has such an authorization, which under the authorization is the law, then this act is exempting that agency from a judicial review or a passing upon that evidence, regardless of the kind of evidence it may be.

Mr. WALTER. Mr. Chairman, will the gentleman yield?

Mr. RUSSELL. I am glad to yield to the gentleman.

Mr. WALTER. The gentleman is not seriously contending that an agency decision based upon a mere scintilla of evidence would hold up?

Mr. RUSSELL. If the law has made it such, it will hold up under this very phrase that I have just read. That is what I am afraid of.

Mr. WALTER. Well, the very measure now under consideration is designed to prevent that sort of thing, and will prevent it.

Mr. RUSSELL. But this is the thing I am afraid of, that is, giving life to that power which the measure is supposed to take away.

There is another bill pending in this House, a very controversial bill. Perhaps you heard of it this week on Calendar Wednesday, where a provision is embodied in that bill which I do not believe 25 Members—10 Members—not 5 Members—if they understood the legal effect of that provision, would vote for the bill with that in it, because they would be cutting off their own noses and denying themselves a right which they hold near and dear. That same provision is embodied in that bill. If it becomes law, the law making that scintilla of evidence binding upon the court, then this bill will not take care of it. That is my only objection to this bill. I do not want to tie the hands of the courts, but throughout the years of American history there has developed the most beautiful, the most equitable, the most American jurisprudence known throughout the world, a system of jurisprudence under which each man can go into court where justice, and justice alone, will prevail.

I ask you to look into this question because I am fearful that by this provision you are giving life to that which you think you are destroying.

[p. 5660]

1.16a(3)(c) May 27: Senate concurs in House amendments, p. 5790

[No Relevant Discussion on Pertinent Section]

1.16b JUDICIAL INTERIM RELIEF AND REVIEW OF AGENCY AMENDMENTS

September 6, 1966, P.L. 89–554, §§705, 706, 80 Stat. 393

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule or prejudicial error. [p. 393]

1.16b(1) HOUSE COMMITTEE ON THE JUDICIARY

H.R. REP. No. 901, 89th Cong., 1st Sess. (1965)

TITLE 5, UNITED STATES CODE, "GOVERNMENT ORGANIZATION AND EMPLOYEES"

AUGUST 31, 1965.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. WILLIS, from the Committee on Judiciary,
submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to whom was referred the bill (H.R. 10104) to enact Title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

PRELIMINARY STATEMENT

Purpose.—The purpose of this bill is to restate in comprehensive form, without substantive change, the statutes in effect before July 1, 1965, that relate to Government employees, the organization and powers of Federal agencies generally, and administrative procedure, and to enact title 5 of the United States Code. In the revised title 5, simple language has been substituted for awkward and obsolete terms, and superseded, executed, and obsolete statutes have been eliminated. This bill is a part of the program of the Committee on the Judiciary of the House of Representatives to enact into law all fifty titles of the United States Code.

History.—The statutes that relate to Government personnel begin with the first statute enacted by Congress, 1 Stat. 23. With the growth of the United States and the accompanying growth in the size of the Government's work force and the complexity of their duties, the personnel statutes grew in number and in complexity. Attempts were made periodically to consolidate personnel statutes, but these attempts had only partial success and grew obsolete through the enactment of subsequent statutes. The Commission on Organization of the Executive Branch of the Government

[p. 1]

(Hoover Commission), in its report on personnel and civil service, February 1955, recommended that the Civil Service Commission prepare and that Congress enact a statute to codify the personnel statutes of the United States (Recommendation 17, pp. 82–83). The need for codification of the statutes relating to personnel has also been recognized by the Committees on Post Office and Civil Service of both Houses, the Bureau of the Budget, and the Civil Service Commission.

In June of 1956, the Civil Service Commission directed its General Counsel, L. V. Meloy, to undertake the recodification of title 5. The recodification effort resulted in two earlier bills. H.R. 8748, 86th Congress, 1st session, which was introduced on August 20, 1959, and H.R. 4158, 88th Congress, 1st session, which was introduced on February 25, 1963. Both bills were circulated among the departments and agencies of the Government and, after receipt, consideration, and adoption of the constructive comments submitted, and incorporation of subsequent legislation, the bill was revised into its present form. Throughout the project, close liaison was maintained between the office of general counsel of the Civil Service Commission and Dr. Charles J. Zinn, law revision counsel for the House Committee on the Judiciary.

Inclusion and exclusion of statutes.—Title 5 as revised does not include all the personnel statutes of the United States. Statutes that relate to the employees of only one agency, if not previously in title 5, have not been brought into the title. Statutes relating to civilian employees which apply to more than one agency are included in title 5 regardless of where they may have appeared previously. Some of these statutes also apply to members of the uniformed service.

Statutes that are temporary in nature are omitted from title 5. A citation to each of these statutes which was in effect before July 1, 1965, is provided in table III.

[p. 2]

SECTION 705

Derivation:	United States Code	Revised Statutes and Statutes at Large
	5 U.S.C. 1009 (d)	June 11, 1946, ch. 324, § 10 (d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

SECTION 706

Derivation:	United States Code	Revised Statutes and Statutes at Large
	5 U.S.C. 1009 (e)	June 11, 1946, ch. 324, § 10 (e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report. [p. 17]

1.16b (2) SENATE COMMITTEE ON THE JUDICIARY

S. REP. No. 1380, 89th Cong., 2d Sess. (1966)

TITLE 5. UNITED STATES CODE "GOVERNMENT ORGANIZATION AND EMPLOYEES"

JULY 21, 1966.—Ordered to be printed

Mr. ERVIN, from the Committee on Judiciary,
submitted the following

REPORT

[To accompany H.R. 10104]

The Committee on the Judiciary, to which was referred the bill (H.R. 10104), to enact title 5, United States Code, "Government Organization and Employees," codifying the general and permanent laws relating to the organization of the Government of the United States and to its civilian officers and employees, having considered the same, reports favorably thereon, with amendments, and recommends that the bill, H.R. 10104, as amended, do pass. [p. 1]

SECTION 705

Derivation:	**United States Code**	**Revised Statutes and Statutes at Large**
	5 U.S.C. 1009 (d)	June 11, 1946, ch. 324, § 10 (d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of the report. [p. 33]

SECTION 706

Derivation:	**United States Code**	**Revised Statutes and Statutes at Large**
	5 U.S.C. 1009 (c)	June 11, 1946, ch. 324, § 10 (e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report. [p. 34]

1.16b (3) CONGRESSIONAL RECORD

1.16b(3)(a) VOL. 111 (1965), Sept. 7: Passed House, p. 22954

[No Relevant Discussion on Pertinent Section]

1.16b(3)(b) VOL. 112 (1966), July 25: Amended and passed Senate, pp. 17010, 17011

[No Relevant Discussion on Pertinent Section]

1.16b(3)(c) VOL. 112 (1966), Aug. 11: House concurs in Senate amendments, p. 19077

[No Relevant Discussion on Pertinent Section]

1.17 PER DIEM, TRAVEL AND TRANSPORTATION EXPENSES; EXPERTS AND CONSULTANTS; INDIVIDUALS SERVING WITHOUT PAY, AS AMENDED

5 U.S.C. §5703 (1966)

[Referred to in 15 U.S.C. §1475(b)]

(See, "General 1.15a–1.15d (3)(c)" for legislative history)

PER DIEM, TRAVEL, AND TRANSPORTATION EXPENSES; EXPERTS AND CONSULTANTS; INDIVIDUAL SERVING WITHOUT PAY

5 § 5703.

(a) For the purpose of this section, "appropriation" includes funds made available by statute under section 849 of title 31.

(b) An individual employed intermittently in the Government service as an expert or consultant and paid on a daily when-actually-employed basis may be allowed travel expenses under this subchapter while away from his home or regular place of business, including a per diem allowance under this subchapter while at his place of employment.

(c) An individual serving without pay or at $1 a year may be allowed transportation expenses under this subchapter and a per diem allowance under this section while en route and at his place of service or employment away from his home or regular place of business. Unless a higher rate is named in an appropriation or other statute, the per diem allowance may not exceed—

(1) the rate of $25 for travel inside the continental United States; and

(2) the rates established under section 5702(a) of this title for travel outside the continental United States.

(d) Under regulations prescribed under section 5707 of this title, the head of the agency concerned may prescribe conditions under which an individual to whom this section applies may be reimbursed for the actual and necessary expenses of the trip, not to exceed an amount named in the travel authorization, when the maximum per diem allowance would be much less than these expenses due to the unusual circumstances of the travel assignment. The amount named in the travel authorization may not exceed—

(1) $40 for each day in a travel status inside the continental United States; or

(2) the maximum per diem allowance plus $18 for each day in a travel status outside the continental United States.
Pub.L. 89–554, Sept. 6, 1966, 80 Stat. 499; and amended Pub.L. 91–114, § 2, Nov. 10, 1969, 83 Stat. 190.

1.18 FEDERAL WATER POLLUTION CONTROL ACT, AS AMENDED

33 U.S.C. §1254(e)(1)–(2)

Collection and dissemination of scientific knowledge on effects and control of pesticides in water

(l) (1) The Administrator shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than January 1, 1973, develop and issue to the States for the purpose of carrying out this chapter the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

(2) The President shall, in consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, conduct studies and investigations of methods to control the release of pesticides into the environment which study shall include examination of the persistency of pesticides in the water environment and alternatives thereto. The President shall submit reports, from time to time, on such investigations to Congress together with his recommendations for any necessary legislation.

June 30, 1948, c. 758, Title I §104, as added Oct. 18, 1972, Pub.L. 92–500, 32, 86 Stat. 822.

1.18a THE WATER QUALITY IMPROVEMENT ACT OF 1970

April 3, 1970, P.L. 91–224, §105(L), 84 Stat. 112

AN ACT

To amend the Federal Water Pollution Control Act, as amended, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—WATER QUALITY IMPROVEMENT

SEC. 101. This title may be cited as the "Water Quality Improvement Act of 1970".

SEC. 105.

* * * * * * *

"(1) (1) The Secretary shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than two years after the effective date of this subsection, develop and issue to the States for the purpose of adopting standards pursuant to section 10(c) the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

[p. 112]

"(2) For the purpose of assuring effective implementation of standards adopted pursuant to paragraph (1) the President shall, in consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, conduct a study and investigation of methods to control the release of pesticides into the environment which study shall include examination of the persistency of pesticides in the water environment and alternates thereto. The President shall submit a report on such investigation to Congress together with his recommendations for any necessary legislation within two years after the effective date of this subsection."

(3) in redesignated subsection (m) (4) by striking out the words "and June 30, 1969," and inserting in lieu thereof "June 30, 1969, June 30, 1970, and June 30, 1971,";

(4) by amending the first sentence of redesignated subsection (n) to read as follows: "There is authorized to be appropriated to carry out this section, other than subsection (g) (1) and (2), not to exceed $65,000,000 per fiscal year for each of the fiscal years ending June 30, 1969, June 30, 1970, and June 30, 1971. There is authorized to be appropriated to carry out subsection (g) (1) of this section $5,000,000 for the fiscal year ending June 30, 1970, and $7,500,000 for the fiscal year ending June 30, 1971 There is authorized to be appropriated to carry out subsection (g) (2) of this section $2,500,000 per fiscal year for each of the fiscal years ending June 30, 1970, and June 30, 1971.".

[p. 113]

1.18a (1) HOUSE COMMITTEE ON PUBLIC WORKS

H.R. REP. No. 91–127, 91st Cong., 1st Sess. (1969)

WATER QUALITY IMPROVEMENT ACT OF 1969

MARCH 25, 1969.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. FALLON, from the Committee on Public Works,
submitted the following

REPORT

[To accompany H.R. 4148]

The Committee on Public Works, to whom was referred the bill (H.R. 4148) to amend the Federal Water Pollution Control Act, as amended, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

The amendment strikes out all after the enacting clause and inserts a substitute text which appears in italic type in the reported bill.

[p. 1]

(1) (1) The Secretary shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than two years after the effective date of this subsection, develop and issue to the States for the purpose of adopting standards pursuant to section 10(c) the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

(2) For the purpose of assuring effective implementation of standards adopted pursuant to paragraph (1) the President shall, in consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, conduct a study and investigation of methods to control the release of pesticides into the environment which study shall include examination of the persistency of pesticides in the water environment and alternatives thereto. The President shall submit a report on such investigation to Congress together with his recommendations for any necessary legislation within two years after the effective date of this subsection. [p. 11]

1.18a (2) SENATE COMMITTEE ON PUBLIC WORKS

S. REP. No. 91–351, 91st Cong., 1st Sess. (1969)

AMENDING THE FEDERAL WATER POLLUTION CONTROL ACT, AS AMENDED, AND FOR OTHER PURPOSES

AUGUST 7 (legislative day, AUGUST 5), 1969.— Ordered to be printed

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Mr. MUSKIE, from the Committee on Public Works,
submitted the following

REPORT

[To accompany S. 7]

The Committee on Public Works, to which was referred the bill (S. 7), having considered the same, reports favorably thereon with amendments and recommends that the bill (as amended) do pass.

INTRODUCTION

S. 7, as reported, includes three titles, the first two of which would amend the Federal Water Pollution Control Act, establish an environmental policy for Federal public works projects and provide for the establishment of an Office of Environmental Quality.

Title I of this legislation would provide specific approaches for dealing with particular kinds of water pollution problems and directing that additional studies be made with regard to some of their more complex aspects.

For the first time the President would have power and authority to deal with disastrous oil spills which threaten serious injury to the Nation's waters and beaches.

The bill also breaks new ground by requiring compliance with water quality standards by all activities over which the Federal Government has direct control or for which Federal licenses or permits are required. Discharges of sewage from vessels which foul many of the Nation's marinas, harbors, and ports will be subject to control measures.

Authority would be provided to designate those hazardous substances, the discharge of which into the Nation's waters, presents a substantial endangerment to health and welfare.

Authorization for continued research under the act are provided as is new authority to solve specific pollution problems caused by eutrophication (the natural process of aging of lakes) and the acid mine drainage.

[p. 1]

Title II of this bill sets forth a fundamental procedure to coordinate Federal, and federally assisted public works activities to assure adequate consideration of the environmental policies set by the Water Quality Act, the Air Quality Act, and the Solid Waste Disposal Act. This title of S. 7, as reported, is designed to bring coherent and integrated management of those environmental policies into the programs of the Federal Government.

Title III includes provisions for acquiring land for use of the U. S. Senate.

The provisions, their ramifications and the intent of the committee will be discussed in detail by title.

[No Relevant Discussion on Pertinent Section] [p. 2]

1.18a (3) COMMITTEE OF CONFERENCE

H.R. REP. No. 91–940, 91st Cong., 2d Sess. (1970)

WATER QUALITY IMPROVEMENT ACT OF 1970

MARCH 24, 1970.—Ordered to be printed

Mr. FALLON, from the committee of conference,
submitted the following

CONFERENCE REPORT

[To accompany H.R. 4148]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 4148) to amend the Federal Water Pollution Control Act, as amended, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

* * * * * * *

Conference substitute [p. 1]

Section 105 of the conference substitute amends section 5 of the Federal Water Pollution Control Act as follows:

(1) By relettering the last two subsections and inserting after subsection (f) new subsections (g) through (l).

(2) The new subsection (g) provides the same authority with respect to training of personnel as was provided by the Senate amendment in its amendment to section 5(g).

The new subsection (h) provides for the same authority with respect to lake eutrophication as was contained in the Senate amendment. It would authorize financial assistance for the construction of publicly owned research facilities by public agencies, including publicly owned universities.

The new subsection (i), relating to research on oil removal problems with the substitution of the requirement that the specifications be developed from time to time, rather than by June 30, 1970, and with other minor changes is the same as the Senate amendment in this regard.

The new subsection (j), relating to marine sanitation device research is essentially the same as the provisions contained in the proposed subsection (j) in the House bill.

The new subsection (k), relating to land acquisition, is essentially the same as the comparable provisions in both the House bill and Senate amendment.

The new subsection (1) is essentially the same as the proposed subsection (j) in the Senate amendment relating to pesticides with the exception that reference to criteria has been deleted, and the term "scientific knowledge" substituted therefor, and the requirement of making the study on pesticides has been placed in the President rather than the Secretary. The conferees expect that the Secretary will consult with the Secretary of HEW on the health aspects of pesticides and will avoid duplication of the research activities of the Department of HEW

[p. 60]

1.18a (4) CONGRESSIONAL RECORD

1.18a (4) (a) VOL. 115 (1969), April 16: Amended and passed House, p. 9293

[No Relevant Discussion on Pertinent Section]

1.18a (4) (b) VOL. 115 (1969), Oct. 7: Senate debated and amended, pp. 28923–28924, 28987–29008

THE PESTICIDE PERIL—LXII

Mr. NELSON. Mr. President, the fine publications sponsored by our country's conservation organizations have been on the forefront of informing concerned citizens regarding the threat to our wildlife and our total environment from persistent pesticides.

The August–September issue of National Wildlife Magazine includes an editorial which expertly outlines the pesticide issue. Like so many other accounts, the editorial reports on the growing evidence of fish and wildlife destruction from DDT and related pesticides and on the buildup of pesticide residues in man. In the face of this rapidly accumulating data, the editorial strongly states:

> The widespread use of DDT should be halted immediately unless its safety can be proven.

I ask unanimous consent that the editorial be printed in the RECORD.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

OUR POINT OF VIEW, DDT THREATENS YOU!

(By Ed Chaney, Director, Information Services)

Thousands of tons of DDT have been ladled onto lands surrounding Lake Michigan over the past 20 years to combat real, and sometimes imaginary threats from a variety of creepy crawlies.

This perennial application contains poison that moves freely from place to place and retains its toxicity for a guesstimated half century or more. Yet it has become an accepted method of dealing with pests. And over the years—via wind, water and soil — DDT has washed into Lake Michigan from farms, orchards, mosquito swamps, elm-lined streets, flower beds and even from mothproofing by dry cleaners.

Occasionally, someone would wonder at the scarcity of robins after the community elms were doused with DDT to fight Dutch elm disease. Once in a while a few unexplainably dead fish would appear in a nearby creek. And sometimes an article claiming DDT was eating the livers out of eagles and ospreys would turn up on the back page of our paper.

"SILENT SPRING" SILENCED

But compared to the commotion over the surtax, the ABM and getting Johnny ready for graduation, these isolated incidents seemed of little concern to most people. Dr. George Mehren, former Assistant Secretary of Agriculture, summed up the tenor of the times in a statement to a congressional committee in 1968, " . . . the hysteria associated with 'Silent Spring' has effectively subsided."

But then it happened! The Food and Drug Administration put the grabs on more than [p. 28923] 10 tons of Lake Michigan coho salmon en route to family dinner tables. The salmon contained up to 19 parts per million DDT—almost three times the maximum allowed in beef sold for human consumption. Suddenly, the fundamental relationship of DDT to man's position at the top of the natural food chain became an exciting topic of conversation for folks living in the Great Lakes area.

The coho seizures added fuel to the smoldering coals of Rachel Carson's best seller which had already been furiously fanned by a group of citizens and scientists banded together in the "Environmental Defense Fund." Attempting to ban DDT as a water pollutant in the state of Wisconsin, EDF paraded an impressive array of scientists through the national press damning DDT as a heinous, uncontrollable global pollutant.

Reaction to the contaminated coho impoundment was quick. Lacking an established tolerance level for DDT in fish, Secretary Robert Finch of Health, Education and Welfare, quickly set a temporary standard of five parts per million. He also established a commission to study the situation and present recommendations within six months.

HOT COHO

State and Federal fishery biologists predicted DDT levels in this year's crop of Lake Michigan coho would reach that five parts per million by mid-summer and several times that concentration by fall. Because growing fish concentrate DDT in their tissues, biologists hold out little hope that millions of pounds of valuable fish will be safe for consumption by the end of the summer. The United States Bureau of Commercial Fisheries also warned that DDT levels in the lake are so high that reproduction of lake trout, salmon and other species may be in real danger.

Visions of DDT scuttling the $200 million Lake Michigan coho salmon fishing industry brought prompt reaction from the governors of the states surrounding Lake Michigan.

They met and declared there was no immediate DDT health hazard in Lake Michigan. Then they set up several committees to study the problem to see if a tolerance level of 20 parts per million DDT would be safe for humans. (Nobody knows what a really safe limit is. Whether it is 1, 5, 20 or 100 parts per million is an arbitrary judgment.)

Illinois Governor Richard B. Ogilvie announced his intention to continue drinking Lake Michigan water and eating coho salmon.

The Michigan Department of Agriculture "banned" DDT in April. This "ban" was analogous to slamming the barn door behind a horse thief and giving him several years to get out of town since it allows unlimited quantities of DDT to be sold and used in Michigan if the chemical was in transit from the manufacturer by June 27. Consequently, new, homegrown DDT will continue to pollute the air, water, soil, wildlife and people of Michigan for a long time.

It is a disturbing, spooky fact that no one really knows what effects, if any, DDT has on humans. Some eminent scientists maintain it may be difficult, even impossible, to find out until incalculable damage has occurred and it is too late to do anything about it.

CARRIES 12 PARTS PER PERSON

We do know the average American carries around approximately 12 parts per million DDT in his body. Man gets an estimated 90 percent of his DDT from food. We also know it is passed on to the human fetus via the mother's placenta and a nursing mother's milk generally contains more DDT than is allowed in milk you buy at the store.

Laboratory experiments with various animals have shown DDT attacks the central nervous system, upsets body chemistry, distorts cells, accelerates gene mutation, reduces drug effectiveness and affects calcium absorption by the bones.

Hungarian experiments with mice emphasized DDT's cancer-producing potential, and that country recently banned its use. These carcinogenic properties were confirmed by a recent controversial six-year study by the National Cancer Institute which found DDT in mice did cause tumors, most of which ". . . had malignant potential."

A pharmacologist with a leading drug firm says DDT has a deleterious effect on rats' sex hormones, which are essentially the same as man's. Further, the amount of DDT necessary to produce that effect ". . . is well within the range of DDT found in human fat."

All this growing, damning evidence does not *absolutely prove* DDT is having or might have the same effects on the human animal. But Dr. Wayland Hayes, past chief of the Public Health Service toxology section, has said, "In considering the safety of workers who formulate DDT, we must depend largely on animal experiments."

Unfortunately, the evidence damning DDT as a potential threat to mankind, all the laboratory experiments, state and Federal study groups, commissions and exploding public concern, may have little impact.

IT'S BIG BUSINESS

The manufacture of DDT is a $20 million a year business, and pesticide manufacturers also fear the fight over DDT will carry over onto its persistent chlorinated hydrocarbon relatives, heptachlor, lindane, aldrin, endrin, dieldrin, and chlordane which constitute a big part of the industry's $1 billion annual sales.

The pesticide lobby is powerful, experienced and at the slightly disparaging word aimed at DDT, industry spokesmen trot out an impressive array of truths extolling its virtues in fighting disease organisms and agricultural pests throughout the world. No one contests these truths.

But there are substitutes for DDT in the form of safe non-persistent insecticides. Insect sterilization offers much hope for counteracting certain pests, and research has been stepped up on insect predators.

But DDT's apologists continue their campaign that DDT is indispensable to the welfare of mankind and get away with it. They know from past experience that the public's memory is short and the people who make the laws and buy the products don't read history books. The decisions will be made behind the scenes.

Agriculture committees in state and Federal government are almost universally dominated by farm and pesticide-oriented legislators. These committees are commonly considered rubber stamps for all but the most offensive industry pleas and graveyards for regulatory bills.

DDT's proponents seem willing to write off the growing list of threatened wildlife including the bald eagle, osprey, peregrine falcon, eider duck, bermuda petrel, brown pelican and even the sportsman-revered mallard duck. During the EDF hearing in Madison, spokesmen for the National Agricultural Manufacturers Association said, ". . . the damage is not as severe as conservationists claim." One of their arguments is that "DDT inhibits the reproduction of birds . . . but these are primarily birds of prey, and very small numbers are involved." And, "A person whose thing is studying the peregrine falcon is concerned only about every little thing that might happen to his bird."

CAN'T PROVE HUMAN EFFECTS

When the question of DDT's possible effects on humans is raised, their answers boil down to "prove it." Despite the overwhelming, growing scientific evidence that portends frightening effects on man, DDT's fans are willing to gamble. And they have graciously volunteered the rest of the world.

The already dangerous and climbing levels of DDT in the food fish of Lake Michigan may be a grim hint of what is to come. Even if not another ounce of DDT were applied anywhere in the world beginning today, some experts guess it would be at least 25 years before the concentrations in the environment begin to level off. However, researchers have revealed a great deal of variability in the chemical's persistence depending upon local conditions.

Our exploding technology now keeps some men alive with artificial hearts and puts others on the moon. What unknown secrets will we discover about the 12 parts per million DDT we all carry in our bodies? At this level, the FDA would rule the average American unfit for human consumption.

John Gottschalk, Director of the Bureau of Sports Fisheries and Wildlife, said "What is happening in Lake Michigan is an indication of what to expect elsewhere. There will be a day, and it may not be until the year 2000, when *we* are the coho salmon."

The widespread use of DDT should be halted immediately unless its safety can be proven.
[p. 28924]

WATER QUALITY IMPROVEMENT ACT OF 1969

The Senate resumed the consideration of the bill (S. 7) to amend the Federal Water Pollution Control Act, as amended, and for other purposes.

Mr. CURTIS. Mr. President, I have an amendment at the desk, and I ask that it be read.

The PRESIDING OFFICER. The amendment will be stated.

The assistant legislative clerk read as follows:

> On page 66, line 6, strike out the word "two" and insert "three"; and in line 7, strike out the word "two" and insert "three".

Mr. CURTIS. Mr. President, under section 16(c) (6) it is provided that for any facility being constructed under a Federal license on the date of enactment of S. 7, no certification under section 16(c) (1) is required for any Federal operating license necessary for such facilities, if such operating license is issued within 2 years following the date of enactment. The subsection further provides that after 2 years, the licensee must provide certification or see its operating license terminate.

This provision is directed principally at facilities licensed under the Atomic Energy Act and is designed to require those facilities to comply with applicable water quality standards particularly as they relate to thermal pollution. This objective is laudible and I support it. However, the 2-year period of time for facilities being constructed to revise their specifications is possibly too short. The installation of facilities necessary to achieve compliance with water quality standards involves millions of dollars and requires considerable time for design and construction. I, therefore, submit, and the basis of my amendment is, that the 2-year time period in order that facilities under the provisions of subsection 16(c) (6) be given added time to achieve necessary compliance.

I think this amendment is necessary to avoid undue hardship while at the same time achieving compliance with water quality standards. The amendment would merely extend the time 1 year.

I urge the adoption of the amendment. It is my hope that the distinguished chairman of the committee, who is in charge of the bill, will see fit to accept it.

Mr. MUSKIE. Mr. President, I have discussed this amendment with the distinguished Senator from Nebraska and the distinguished Senator from Delaware (Mr. BOGGS). It does not in any way change the thrust of this provision of the bill or the principle underlying it. It is a question of allowing more time for plants that began their construction before the date of enactment of this bill to adjust to its requirements. I have no objection to the amendment.

Mr. CURTIS. I thank the distinguished Senator very much.

I ask for a vote.

The PRESIDING OFFICER. The question is on agreeing to the amendment of the Senator from Nebraska.

The amendment was agreed to.

AMENDMENT NO. 132—ADDITIONAL COSPONSORS

Mr. NELSON. Mr. President, I call up my amendment No. 132, and I ask unanimous consent that the names of the following Senators be added as cosponsors of the amendment: Mr. MUSKIE, Mr. RANDOLPH, Mr. BAYH, Mr. BROOKE, Mr. BURDICK, Mr. CANNON, Mr. CASE, Mr. CHURCH, Mr. CRANSTON, Mr. DODD, Mr. EAGLETON, Mr. GOODELL, Mr. GRAVEL, Mr. HARRIS, Mr. HART, Mr. HARTKE, Mr. HOLLINGS, Mr. INOUYE, Mr. JAVITS, Mr. KENNEDY, Mr. MAGNUSON, Mr. MCGEE, Mr. MCGOVERN, Mr. MCINTYRE, Mr. MONDALE, Mr. MOSS, Mr. PELL, Mr. PROXMIRE, Mr. TYDINGS, Mr. WILLIAMS of New Jersey, and Mr. YOUNG of Ohio.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment will be stated.

The assistant legislative clerk read as follows:

AMENDMENT NO. 132

On page 69, line 7, in lieu of "(k)" insert "(l)".

On page 72, between lines 8 and 9, insert the following: "(j) (1) The Secretary shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than two years after the effective date of this subsection, develop and issue to the States for the purpose of adopting standards pursuant to section 10(c) criteria reflecting the latest scientific knowledge useful in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such criteria whenever necessary to reflect developing scientific knowledge.

"(2) For the purpose of assuring effective implementation of standards adopted pursuant to paragraph (1) the Secretary shall, in consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, conduct a study and investigation of methods to control the release of pesticides into the environment, which study shall include examination of the persistency of pesticides in the water environment and alternatives thereto. The Secretary shall submit a report on such investigation to Congress together with his recommendations for any necessary legislation within two years after the effective date of this subsection."

On page 72, line 9, in lieu of "(j)" insert ("k").

Mr. NELSON. Mr. President, in a recent grim scenario, a noted ecologist, Dr. Paul Ehrlich, projects the [p. 28987] end of the oceans as a significant source of life in 10 years. Mass starvation of mankind follows, then war.

Dr. Ehrlich says if present trends continue, such a disastrous end to life on earth could be perilously near.

Not surprisingly, pesticides were a key part of Dr. Ehrlich's setting for disaster. As the first dramatic danger signal of the threat to life in the sea, the ecologist cites the report in 1968 that DDT slows down photosynthesis in marine plant life.

In his article in Ramparts magazine, Dr. Ehrlich spells out the implications:

> It was announced in a short paper in the technical journal, Science, but to ecologists it smacked of doomsday. They knew that all life in the sea depends on photosynthesis, the chemical process by which green plants bind the sun's energy and make it available to living things. And they knew that DDT and similar chlorinated hydrocarbons had polluted the entire surface of the earth, including the sea.

Events moved inexorably from that point on in the Ehrlich scenario, with pesticides continuing to play a major role. Through the present, all events he cites are fact. For the future, he bases his conjecture on current trends.

Implausible to project the end of the oceans and man in 10 years? There have been too many "implausibles" or "impossibles" in this century that have come true: World War I, World War II, the atomic bomb, the hydrogen bomb, the war in Vietnam, the riots in American cities and universities, the assassination of a President, a candidate for President, and an international civil rights leader. One can readily understand the perceptive comment of Nobel Prize Winning Biologist D.. George Wald that today's youth are the first generation that believes, and with good reason, that there may be no future.

And as we move into the last third of the 20th century, it has become dramatically clear that the danger we face from the destruction of the habitat and life support systems of man by overpopulation and pollution is as great as that from nuclear holocaust.

Only a short time ago, anyone discussing our environmental problems could not have thought to include pesticides as a major threat. Like other technological innovations that have brought shocking byproducts, pesticides have come into being and then into mass use with stunning speed.

DDT DISCOVERED

For instance, DDT was first formulated in 1874. But its properties as an insecticide were not discovered and put into use until World War II. Almost immediately, DDT became known as the miracle insecticide that helped control tropical disease and win the war.

Since then, thousands of millions of pounds of DDT and other synthetic pesticides have been applied to millions of acres to regulate economic plant or animal populations to protect food and fibre crops, reduce vectors of disease, and abate pest nuisances.

Their fame spread as did their use. Billions upon billions of pests have fallen victim to their dust, spray, or powder.

But new strains of pests developed with increased resistance to DDT and other common pesticides.

Too often, instead of seeking more effective, more selective means of pest control, the reaction of many users has been to apply more, perhaps two, three, 10 times as much, to overcome the pest's newly attained resistance.

Today, nearly 900 million pounds of pesticides, including insecticides, herbicides, fungicides, rodenticides, and fumigants, are sold annually in the United States alone, more than 4 pounds for every American. Last year, the sales of pesticides increased some 10 percent over the previous year, and by 1985, it is estimated that they will increase another sixfold.

Reports indicate that about 1 acre of every 10 in America is treated with an average of nearly 4 pounds of pesticides every year.

And in little over 25 years, DDT and other pesticides have been spread by the soil, wind, the tide, and the chain of life itself to the farthest reaches of the earth. This and other highly persistent, mobile pesticide compounds are now one of the most easily distinguishable marks of the presence of man.

GLOBAL CONTAMINATION

Six years ago, two U.S. scientists hypothesized that the entire globe may already have been contaminated by DDT. To find out, they went to Antarctica. If any area of the world were to be free of pesticide residues, it would be that isolated continent, where there are no pests, few animals or plants, and where the nearest pesticide use is thousands of miles away.

The scientists found pesticide residues in four of 16 Adelie penquin they tested, four of 16 Wedell seals, and 15 of 16 skuas—a sea bird. The evidence was inescapable. Worldwide pesticide contamination was confirmed.

Another scientist, who measured residues in the Antarctic snow melt, estimated that over the last two and a half decades, about 2,600 tons of DDT could have accumulated in the Antarctic snow and ice.

Scientists have yet to discover exactly how DDT and other pesticides have spread so far, so fast. But some things are clear: DDT, with a half life of 10 years, is remarkably hard to break down, especially in the natural environment where nature has not developed the means to decompose this synthetic compound. And pesticides such as DDT and Dieldrin are highly mobile, able to travel through the environment by any number of means.

The pesticide residues tend to concentrate to progressively higher levels when they are picked up around the globe by tiny organisms, then passed up the food chain.

A well-researched example of this characteristic was documented in California. In order to control a troublesome flying insect that was hatching in a lake in that State, the water was treated with the insecticide DDD—similar to DDT—yielding a concentration of 0.02 parts per million. Plankton, which includes microscopic waterborne plants and animals, accumulated the DDD residues at five parts per million. Fish eating the plankton concentrated the pesticide in their fat to levels from several hundred to up to 2,000 parts per million. Grebes, diving birds similar to loons, fed on the fish and died. The highest concentration of DDD found in the tissues of the grebes was 1,600 parts per million.

If it were simply a case of another compound sprawling over the earth like dirt or air there might be little cause for concern. But the implications of the pervasive pesticide accumulation are far more serious.

ACTIVE AGAINST LIFE

Dr. Charles Wurster, an organic chemist and nationally known pesticide expert assisting the Environmental Defense Fund, likens the pesticide spread to mass use of biocides, agents which are known by scientists as "active against life."

"In general, if an organism has nerves, DDT or Dieldrin can kill it," Wurster believes. He says the action of other hard, chlorinated hydrocarbon pesticides such as Aldrin, Endrin, Heptachlor and Toxaphene is similar. Thus, Wurster says these compounds "are toxic to almost the entire animal world."

During a recent conference on pesticides in Stockholm, evidence was presented that DDT, even in very small quantities, could affect human metabolism. One of the studies cited was Russion research that indicated that workers whose jobs bring them in contact with DDT and other organochlorine pesticides were found to suffer from changes in the liver which slowed down the elimination of wastes from the body.

A major study published this summer by the National Cancer Institute found that at least 11 pesticides out of 123 chemical compounds tested induced a significantly increased incidence of tumors in laboratory animals. The 11 tumorigenic compounds included five insecticides p.p' —DDT, Mirex, bis(2-chlorethyl)-ether, chlorobenzilate and strobane; five fungicides PCNB, Avadex, Ethyl selenac, ethylene thiourea, and bis (2-hydroxyethyl) dithiocarbamic acid potassium salt; and one herbicide N-(hydroexthyl) hydrazine.

While the researchers have reserved judgment on whether these pesticides should be considered as a potential cause of cancer, it appears very certain that growing concern about the threat of pesticides to human health is entirely warranted.

In 25 years, then, we have turned loose on the earth a massive dose of compounds that can cripple or kill, and which are tragically indiscriminate in their attacks. When DDT is applied to do one job, it lingers and accumulates in the environment as a toxic threat to fish, wildlife, and possibly even to man.

Already, the petrel of Bermuda, the bald eagle and peregrine falcon of America and the blue shell crab of the sea are each being pushed to the brink of extinction by the spread of pesticides through our environment.

Like so many other environmental disasters, it is shocking that this has happened. But what is almost beyond belief is that, even from the beginning, the pesticide dangers were known.

The fact that DDT would kill wildlife was determined in 1945, the same [p. 28988] year that the pesticide was released for civilian use. The discovery was made by wildlife biologists working in U. S. Department of Agriculture studies.

From that point on, scientific concern continued to mount worldwide, but, unfortunately, the debate simmered out of the public eye for almost two decades.

"SILENT SPRING"

Then, in 1962, came a dramatic turning point: The New Yorker magazine serialized a book by a lady biologist in the U.S. Department of Interior that brought home to the public for the first time the rapidly building dangers from pesticide misuse. The book was "Silent Spring," by Miss Rachel Carson.

Challenging the myth that pesticides were the panacea that they were being proclaimed, Miss Carson said:

> **As crude a weapon as the cave man's club has been hurled against the fabric of life.**

Translated into 30 languages, the book was read by millions in the United States and around the world. Almost single-handedly, it bridged the gap between the scientist and the concerned citizen which so often exists in our complex society today.

In 1963, Miss Carson testified before the Senate Government Operations Committee, chaired by our colleague, Senator ABRAHAM RIBICOFF.

Also in 1963, a report by the President's Science Advisory Committee, chaired by Jerome Wiesner, concluded that the goal of our national efforts should be "elimination of the use of persistent toxic insecticides."

In the following Congress, I initially introduced legislation to ban the interstate sale and shipment of DDT. I subsequently introduced the same legislation in the 90th and 91st Congresses, and similar measures have since been introduced in the House. During the past three Congresses, no committee hearings have been held on these proposals.

However, interest around the country in achieving effective pesticide controls continued to build, and there was growing citizen impatience with the failure of State and Federal agencies to act.

Yet, despite the urgent warnings and concern, our government agencies have failed miserably to respond responsibly to this massive problem. Not a single Federal office has taken any significant action that would lead to the goal of "eliminating" the use of persistent toxic pesticides that was established 6 years ago by the Presidential committee.

AGENCIES INEFFECTIVE

The fact is that the Federal Government has been perpetuating this grave environmental and health problem, rather than resolving it.

It was recently revealed that the U.S. Department of Agriculture, which is charged with regulating pesticide use, has been sponsoring a program with the Air Force and other Government agencies under which 250,000 pounds of dieldrin has been applied to 56 military and civilian airports across the country over the past 15 years.

This program, which has raised strenuous objection from scientists, was twice reviewed and approved by the interdepartmental Federal Committee on Pest Control.

The committee, which is billed as the regulator of Federal pesticide use, recently confirmed that the General Services Administration and the Office of the Capitol Architect have not even submitted their pesticide programs to the committee for review.

Clearly, the Federal effort at regulating itself has been as ineffective as has the regulation of pesticide use at large.

Ironically, a number of States, as well as several foreign countries, have shown far greater willingness to act than the U.S. Government. DDT has been banned by the States of Michigan and Arizona, and overseas, by Denmark and Sweden. And countless cities and towns have stopped using DDT in their mosquito control and tree disease eradication programs. In addition, a number of States, including Wisconsin, and California, are considering steps to drastically restrict the use of DDT and other hard pesticides within their borders.

These recent State and local measures are a reflection of the citizen demand for action that has been building at a heartening pace.

For instance, the idea of creating an Environmental Defense Fund grew out of a suit filed in April 1966, against the Suffolk County Mosquito Control Commission, by Victor J. Yannacone, Jr., a young lawyer, on behalf of his wife, Carol, and all other people of Suffolk County, Long Island. The court challange was based on a report that a DDT dumping by commission employees was the cause of a fish kill in a nearby lake.

The New York suit was successful in leading to a temporary ban on the use of DDT in Suffolk County by public agencies, and gained public recognition as one of the first attempts to argue that the citizen has the right under law to protect his environment.

Then in November of 1967, the Environmental Defense Fund brought its first court action in its own name, seeking to prevent the use of dieldrin in a Japanese-beetle control project in Michigan by the Michigan and U.S. Departments of Agriculture. Several Michigan Conservation Department affidavits, including one holding that the spraying would threaten Lake Michigan's new coho salmon fishery, were disallowed on a technicality when the State attorney general's office refused to let the department officially enter the case. The tragic results of pesticide misuse for the coho were to become evident 3 years later.

In the Michigan suit, Yannacone got a temporary order from the State court of appeals to stop the dieldrin spraying, but this injunction was dissolved after a 6-hour trial.

WISCONSIN DDT HEARINGS

One year later, the battleground shifted to the other side of Lake Michigan, to Madison, Wis., where citizen groups and the Environmental Defense Fund joined forces in a petition asking the State Department of Natural Resources to ban the use of DDT in the State under any circumstances where the pesticide can enter the world circulation patterns and further contaminate the biosphere. With EDF, the petitions groups were the Citizens Natural Resources Association of Wisconsin and the Wisconsin division of the Izaak Walton League.

In the State hearing which began last December, the Alliance of Concerned Scientists and Lawyers presented extensive testimony outlining the growing pollution of the environment by persistent pesticides in the chlorinated hydrocarbon family.

Dr. Robert W. Risebrough, an environmental scientist at the University of California at Berkeley, stated that the effect of pesticides on man may be very serious. He said that man accumulates 12 parts per million of DDT in his fatty tissues before the body discharges it. He said that this is enough to stimulate enzyme production, which acts as a catalyst for bodily processes, such as digestion. Risebrough added that the death of some birds has been traced to enzyme induction by DDT, impairing their ability to reproduce.

Dr. Charles F. Wurster, Jr., an organic chemist at the State University of New York, Stonybrook, testified on the range of the pesticide residues through the world.

Other witnesses have testified that DDT goes into the atmosphere along with evaporating water, builds up to extremely high levels in predator birds and animals, and has caused new insect problems by killing predators that once held those insects in check.

Dr. Joseph Hickey, a University of Wisconsin wildlife ecologist, said that DDT has been linked to reproduction failures of certain birds, including the eagle, the osprey, and the peregrine falcon. Dr. Hickey and other researchers have traced the presence of pesticide residues to a decrease in weight and thickness of the shells of eggs produced by these birds.

In related testimony, Lucille Stickel, the pesticide research coordinator of the Interior Department's Patuxent Wildlife Research Center, stated that the presence of small quantities of DDT and its derivative DDE in the diets of mallard ducks decreased eggshell thickness, increased egg breakage, and decreased overall reproductive success.

Although the second half of the hearings, held last spring, was billed as the time for the defense against the arguments of the environmentalists, the pesticide industry, which historically has promoted more pesticide use and fought new controls, made a weak defense.

Industry witnesses who were knowledgeable about the environmental impact of pesticides were few and far between. Instead, defense witnesses relied on shopworn repetitions of the past triumphs of DDT and trotted out research from a decade ago which purported to show that the health of pesticide workers was not impaired by constant exposure to the compounds.

In fact, witnesses for the defense often provided the environmentalists with valuable evidence to support their contentions. For example, a Shell Development Co. scientist confirmed the fact that DDT does not remain in the soil, but has a great deal of mobility and persistence which enables it to infiltrate the atmosphere, the waters,

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and the total environment.

Another witness for the DDT defense, a U.S. Department of Agriculture pesticide official, admitted that his agency relies almost totally on industry claims regarding health and environmental effects.

An initial decision on the environmentalists' petition is expected before the end of this year.

COHO SALMON SEIZED

Midway through the Wisconsin hearings, a new and dramatic confirmation of pesticide dangers was announced to Wisconsin and the Nation: The U.S. Food and Drug Administration was seizing 28,150 pounds of frozen Lake Michigan Coho salmon because it said high DDT and dieldrin residues had made the fish unfit for human consumption.

According to the FDA, the concentration of DDT in the salmon was found to be up to 19 parts per million, while the accumulation of dieldrin was just short of 0.3 of a part per million, both levels considered hazardous by the FDA and the World Health Organization.

The contamination of the Coho challenges a basic foundation of the pesticide argument that has been sounded for a quarter of a century—that pesticide use is invariably an economic benefit, that is to say, an "economic" poison.

One might ask the commercial fisherman who sees the Coho salmon as a great new opportunity in a lamprey-ravaged Great Lakes fishery whether the current pesticide approach is "economic". One might also ask the same question of the resort owner in northern Michigan who saw his business skyrocket with the introduction of the salmon in Lake Michigan in 1965.

One might ask the economic benefit question of the Michigan Department of Natural Resources, which during the 1966 EDF suit attempted to warn of the danger to the Coho, and which has invested millions of dollars to plant Coho salmon fry in Lake Michigan only to see nearly a million of the fry killed by the pesticide contamination. And, finally, one might ask the economic effects if the national recreation resource of the Great Lakes, enhanced by millions of State and Federal tax dollars, is further damaged by the pesticide peril to the salmon and other lake resources, including the very quality of the water itself.

Ironically, the Lake Michigan Water Pollution Conference in 1968 was warned that the pesticide concentration in Lake Michigan was at the crisis point. W. F. Carbine, Great Lakes Regional Director for the Bureau of Commercial Fisheries, stated:

> Lake Michigan has the highest concentration of pesticides of any of the Great Lakes, which now are only slightly below levels that are known to be injurious to man or aquatic life. . . . A continuation at high levels or an upsurge in pesticide application in the Lake Michigan Basin could increase the pesticide concentration prevailing in the open lake from the present non-lethal level to a lethal value.

The evidence is already clear that for the United States, the Lake Michigan tragedy is only the beginning. On June 17 of this year, 52 cases of jack mackerel, caught on the west coast, were confiscated in New York by the Food and Drug Administration because of high DDT levels. The mackerel appeared to be the first ocean fish from American waters to be declared unfit for human food because of DDT.

In several central and northern New York lakes, lake trout have either been eliminated, or their reproduction seriously impaired, because of high pesticide levels. DDT concentrations in the lake trout of up to 3,000 parts per million in the fatty tissues have already been reported.

NATIONAL PESTICIDE SURVEY

A 2-year national pesticide study recently completed by the U.S. Bureau of Sport Fisheries and Wildlife found DDT in 584 of 590 samples of fish taken from 45 rivers and lakes across the United States.

The study results showed DDT ranging up to 45 parts per million in the whole fish, a count more than nine times higher than the current FDA guideline level for DDT residues in fish.

Residues of DDT reached levels higher than the FDA's temporary limit of five parts per million in 12 of the rivers and lakes, including the Hudson in New York; the Delaware; the Cooper in South Carolina; St. Lucie Canal and the Apalachicola in Florida; the Tombigbee in Alabama; the Rio Grande in Texas; Lake Ontario; Lake Michigan; the Arkansas and the White in Arkansas; and the Sacramento in California.

Residues of dieldrin, a pesticide even more toxic to humans than DDT, were found in excess of the 0.3 parts per million FDA limit in 15 rivers and lakes including the Connecticut; the Hudson; the Delaware; the Savannah in Georgia; the Apalachicola; the Tombigbee; the Rio Grande; Lake Ontario; Lake Huron; the Illinois in Illinois; the Arkansas and the White; the Red River in Minnesota; the San Joaquin in California; and the Rogue in Oregon.

In summary, the comprehensive survey found DDT in almost 100 percent of the fish samples, dieldrin in 75 percent, heptachlor and/or heptachlor epoxide in 32 percent, and chlordane in 22 percent.

Related research over the 4-year period, ending in 1968, has determined that more than 1,640,000 fish were killed by pesticide pollution in the Nation's waters, the result of pesticide spills or runoff and concentration in our waters. Millions of more fish no doubt went unborn due to reproductive failures caused by pesticides.

Laboratory research has proven that pesticide levels in water, of even the low parts per billion, can be toxic to adult fish. Levels in low parts per trillion have been found to affect reproduction.

Already, the pesticide levels in Lake

Michigan, the most pesticide-polluted of the Great Lakes, are in the low parts per trillion range.

And findings released just this month by the U.S. Public Health Service reported the detection of pesticides in 76 of 79 samples of drinking water supplies around the country. Although the PHS report noted that so far the pesticide levels have not exceeded recommended permissible limits, the health service was concerned. The PHS said:

> The high frequency of occurrence and our lack of knowledge of the long-term health effects of this class of compounds dictate the need for increased surveillance and research as well as for increased recognition of the potential of this problem by state and local health departments.

In summary, the already massive and still accumulating evidence on pesticides makes it clear that these toxic compounds have become one of the most serious problems of our environment, and are threatening even greater worldwide damage. Pesticides have concentrated to the far ends of the earth; they are killing fish and wildlife; they have inhibited fish and wildlife reproduction; high pesticide residues have pushed some fish-feeding birds and other animals to the edge of extinction, and now, there is increasing concern and evidence about the threats posed to man.

The problem of pesticides in the environment is showing up most dramatically and seriously in our rivers and lakes. Although the bulk of pesticide application is on land, the compounds, especially hard pesticides like DDT and dieldrin, are persisting long enough to be carried by agricultural and urban runoff into water bodies. There, as I have pointed out, they enter and are concentrated through the food chain of marine life and fish-feeding birds.

There is little question that pesticides are a grave pollution threat, one which we have barely acknowledged, let alone dealt with. And if we continue to delay action to protect the environment and man from these compounds, I am gravely concerned for the probable consequences.

Fortunately, there is an excellent vehicle already available to us to deal with the pollution aspects of the pesticide problem—the Federal Water Pollution Control Act, and particularly the provisions added by the Water Quality Act of 1965.

PESTICIDE AMENDMENT

It is to this act which my amendment to Senate bill 7 is directed. Most simply stated, the amendment provides congressional direction to the Secretary of the Interior to take certain steps to deal with water pollution problems of pesticides under the authorities granted him by the pollution control statute.

I ask unanimous consent that an analysis of the amendment be printed in the RECORD at this point.

There being no objection, the analysis was ordered to be printed in the RECORD, as follows:

ANALYSIS OF NELSON PESTICIDE POLLUTION AMENDMENT

Under this two-part amendment, the Secretary of the Interior would utilize the authorities granted him by the Federal Water Pollution Control Act to deal with water pollution caused by pesticides.

Part One directs the Secretary to develop and issue to the states within two years water quality criteria for all pesticides. The criteria would list safe pesticide levels in water for public water supplies, propagation of fish and wildlife, recreational purposes, and other legitimate uses.

The criteria would be issued for the purpose of setting pesticide standards as part of the interstate water quality standards already adopted by the 50 states for other pollutants under Federal and state laws.

For the purpose of setting the standards

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Section 10C of the Federal Water Pollution Control Act provides that ". . . if the Secretary or the Governor of any State affected by water quality standards . . . desires a revision in such standards, the Secretary may . . . prepare regulations setting forth standards of water quality to be applicable to interstate waters. . . ."

Under this procedure, the Secretary would ask the states to revise their interstate water quality standards to include pesticide limits. If a state does not act, the Secretary is authorized to set the standards. Also, a state may, on its own, request a revision of its standards.

In addition to serving as a basis for these interstate water quality standards, the pesticide criteria would also give the Secretary a useful tool in ongoing and any future federal-state pollution abatement conferences where pesticide pollution might be occurring.

As is the case with present water quality standards, responsibility for enforcing the pesticide standards would rest primarily with the states under an implementation plan adopted by each state as part of the standards.

In the setting and implementing of the standards, Federal law provides that consideration must be given to their practicability and physical and economical feasibility.

Means of implementing the standards could include: state administrative or legislative action to restrict the use of a pesticide pollutant statewide or in the affected watershed; interstate action; integrated pest control; use of less persistent pesticides; development of agents to decompose pesticides; and biodegradability and toxicity standards on the pesticides themselves.

Part Two of the amendment directs the Secretary of the Interior, in consultation with appropriate Federal agencies and other concerned parties, to conduct a study on methods of controlling the release of pesticides into our nation's lakes and rivers and the environment. The study will include examination of the persistence of pesticides in the water and alternatives thereto. Within two years, the Secretary will submit a report on this study to Congress, together with his recommendations for any necessary legislation.

This study will assist the Secretary in perfecting existing means of dealing with pesticide pollution and in determining new ones.

Mr. NELSON. Mr. President, Part 1 of the amendment requires the Secretary to develop within 2 years water quality criteria for all pesticides. The criteria would set forth the effects of various pesticide levels in water on fish and wildlife, man and the environment. Because they would outline maximum safe levels, they would represent the essential basis for action to deal with the pesticide pollution problem.

Under his existing authorities, the Secretary has already developed criteria for a wide range of pollutants, from municipal sewage to industrial waste, and these are serving as the basis for the interstate water quality standards which have been set by all 50 States as the key to the national pollution cleanup effort. Criteria have been developed for some pesticides, but they are general and incomplete, and technical personnel have advised that 2 years is a reasonable time to allow development of comprehensive pesticide criteria.

STATE STANDARDS INADEQUATE

After a review of the water quality standards already adopted by the States under the Federal act, it is very clear that pesticides are dealt with only in the most general way in the standards, and it is doubtful that this approach will lead to effective control.

For instance, only three States—Alaska, California, and South Dakota—have set specific numerical limits for pesticides in their water quality standards. Two other States—Idaho and Virginia—specifically mention pesticides in toxicity sections of their standards. Otherwise, the State standards deal with pesticides only as they would be covered in general narrative statements on toxicity or by public water supply or aquatic life criteria.

I requested the Federal Water Pollution Control Administration to do a State-by-State summary of pesticide provisions in the water quality standards, and I ask unanimous consent that it be printed in the RECORD at the end of this statement.

The PRESIDING OFFICER (Mr. CRANSTON in the chair). Without objection, it is so ordered.

(See exhibit 1.)

Mr. NELSON. Mr. President, based on the preliminary criteria already developed by the Interior Department, the comprehensive pesticide guidelines required by this amendment would no doubt indicate what level of a specific pesticide in water is hazardous to a specific species of fish. In addition, safe levels for pesticides would no doubt be determined for other water uses, including those of drinking, swimming, and boating.

The comprehensive pesticide criteria would be issued by the Secretary to the States for the purpose of setting pesticide standards as part of the interstate water quality standards already adopted by the States under Federal and State laws.

For the purpose of setting the standards, section 10(c) of the Federal Water Pollution Control Act provides:

> If the Secretary or the Governor of any State affected by water quality standards . . . desires a revision of such standards, the Secretary may . . . prepare regulations setting forth standards of water quality to be applicable to interstate waters. . . .

Under this procedure, the Secretary would ask the States to revise their interstate water quality standards to include pesticide limits. If a State does not act, the Secretary is authorized to set the standards. Also, a State may on its own request a revision of its standards. The Federal law provides that consideration must be given in the standard setting to practicability and physical and economic feasibility.

In addition to serving as a basis for interstate water quality standards, the pesticide criteria would also give the Secretary a useful tool in ongoing and any future Federal-State pollution abatement conferences where pesticide pollution might be occuring.

The step-by-step procedure that would be followed under the Federal Water Pollution Control Act for standard setting and implementation follows:

First. The Secretary, after consultation with interested, concerned parties, would prepare and publish regulations setting forth water quality standards for pesticides, based on the criteria he had developed.

Second. The States would then adopt pesticide standards for their interstate waters, subject to the review and approval by the Secretary as meeting his comprehensive criteria. The States could adopt more stringent standards than provided by the criteria. If the States did not adopt pesticide standards and did not petition the Secretary for a public hearing on the question, the Secretary is authorized to promulgate the standards.

Third. Responsibility for enforcing the standards would rest primarily with the States, under an enforcement plan adopted as part of the standards. Implementation of the present water quality standards for other pollutants generally means the issuance by the States of orders to polluters to take remedial steps. If the orders are not followed, State court action could follow. Issuance of pollution cleanup orders must be preceded by further public hearings.

It is unlikely that action to implement pesticide standards under the water pollution control law would be by court action against pesticide users.

This is true principally because, unlike municipal sewage which is discharged from one point, pesticides usually enter the water in a generalized fashion from a wide range of sources. For instance, DDT may be coming to a river from 100 farms, or 15 towns, in one watershed.

IMPLEMENTATION OF STANDARDS

Fortunately, there are more equitable and efficient means available to implement and enforce pesticide standards, approaches which would be carried out by cooperative efforts between users, pollution control and other pesticide regulatory agencies, and pesticide manufacturers:

First, State administrative or legislative action to restrict or prohibit the use of a pesticide pollutant statewide or in the affected watershed. As pointed out earlier, a number of States, and cities and towns are already taking this approach.

Second, interstate action, through compacts, or the Federal-State pollution control conference provided in Federal law, to restrict or prohibit the use of certain pesticides. For instance, a committee to the Federal-State conference on Lake Michigan made specific recommendations for pesticide limits and other interstate or uniform State actions.

Third, increased use of less persistent pesticides as substitutes for compounds such as dieldrin and DDT which remain in a toxic state for years. This would be coupled with more efficient means of pesticide application. The feasibility of this approach is demonstrated by the fact that for virtually all crops, the U.S. Department of Agriculture lists more than one pesticide as being able to control harmful pests; I ask unanimous consent that a list of readily degradable pesticides prepared by the U.S. Department of Agriculture be printed in the RECORD at this point.

There being no objection, the list was ordered to be printed in the RECORD, as follows:

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READILY DEGRADABLE INSECTICIDES (INCLUDING MITICIDES)

Common name (or trade name*)	Chemical name (or source)	Type of compound
Abate*	0,0-dimethyl phosphorothioate 0,0-diester with 4,4′-thiodiphenol	Organophosphorus.
Aldicarb	2-methyl-2-(methylthio) propionaldehyde 0-(methylcarbamoyl)oxime	Carbamate.
Allethrin	2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-one ester of 2,2-dimethyl-3-(2-methylpropenyl)cyclopropanecarboxylic acid	Pyrethroid.
Azinphosethyl	0,0-diethyl phosphorodithioate S-ester with 3-(mercaptomethyl)-1,2,3-benzotriazin-4(3H)-one	Organophosphorus.
Azinphosmethyl	0,0-dimethyl phosphorodithioate S-ester with 3-(mercaptomethyl)-1,2,3-benzotriazin-4(3H)-one	Do.
Azodrin*	3-hydroxy-N-methyl-cis-crotanamide dimethyl phosphate	Do.
Barthrin	6-chloropiperonyl 2,2-dimethyl-3-(2-methylpropenyl)cyclopropane-carboxylate	Pyrethroid.
Baygon*	o-isopropoxyphenyl methylcarbamate	Carbamate.
Bidrin*	3-dydroxy-N,N-dimethylcrotonamide dimethyl phosphate	Organophosphorus.
Binapacryl	2-sec-butyl-4,6-dinitrophenyl 3-methyl-2-butenoate	Aromatic ester.
Bux*	m-(1-methylbutyl)phenyl methylcarbamate and m-(1-ethylpropyl)-phenyl methylcarbamate (3:1 mixture)	Carbamate.
Carbaryl	1-naphthyl methylcarbamate	Do.
Carbofuran	2,3-dihydro-2,2-dimethyl-7-benzofuranyl methylcarbamate	Do.
Carbophenothion	S-[[(p-chlorophenyl)thio]methyl] 0,0-diethyl phosphorodithioate	Organophosphorus.
Ciodrin*	alpha-methylbenzyl 3-hydroxycrotonate dimethyl phosphate	Do.
Coumaphos	0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	Do.
Dasanit*	0,0-diethyl 0-[p-(methylsulfinyl)phenyl]phosphorothioate	Do.
Demeton	0,0-diethyl S(and 0)-[2-(ethylthio)ethyl] phosphorothioates (mixture)	Do.
Diazinon	0,0-diethyl 0-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate	Do.
Dichlorvos	2,2-dichlorovinyl dimethyl phosphate	Organophosphorus.
Dimethoate	0,0-dimethyl phosphorodithioate S-ester with 2-mercapto-N-methylacetamide	Do.
Dimethrin	2,4-dimethylbenzyl 2,2-dimethyl-3-(2-methylpropenyl)=cyclopropanecarboxylate	Pyrethroid.
Dimetilan	1-(dimethylcarbamoyl)-5-methyl-3-pyrazolyl dimethylcarbamate	Carbamate.
Dioxathion	S,S′-p-dioxane-2,3-diyl 0,0,0′, 0′-tetraethyl phosphorodithioate diphenylamine	Organophosphorus.
Diphenylamine	Diphenylamine	Aromatic amine.
Disulfoton	0,0-diethyl S-[2-(ethyl S-[2-(ethylthio)ethyl] phosphorodithioate	Organophosphorus.
Dursban*	0,0-diethyl 0-3,5,6-trichloro-2-pyridyl phosphorothioate	Do.
Dyfonate*	0-ethyl S-phenyl ethylphosphonodithioate	Do.
EPN	0-ethyl 0-p,nitrophenyl phenylphosphonothioate	Do.
Ethion	S,S′-methylene 0,0,0′,0′-tetraethyl phosphoro dithioate	Do.
Formetanate	m-[[(dimethylamino)methylene] amino] phenyl methylcarbamate	Carbamate.
Galecron*	N′-4-chloro-o-tolyl)-N,N-dimethylformamidine	Aromatic amidine.
Gardona*	2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate	Organophosphorus.
Imidan*	0,0-dimethyl phosphorodithioate S-ester with N-(mercaptomethyl)-phthalimide	Do.
Landrin*	2,3,5-trimethylphenyl methylcarbamate and 3,4,5-trimethylphenyl methylcarbamate (mixture)	Carbamate.
Malathion	diethyl mercaptosuccinate S-ester with 0,0-dimethyl phosphorodithioate	Organophosphorus.
Matacil*	4-(dimethylamino)-m-tolyl methylcarbamate	Carbamate.
Methomyl	S-methyl N-[(methylcarbamoyl)oxy]thioacetimidate	Do.
Methyl parathion	0,0-dimethyl 0-p-nitrophenyl phosphorothioate	Organophosphorus.
Methyl Trithion*	S-[[(p-chlorophenyl)thio]methyl] 0,0-dimethyl phosphorodithioate	Do.
Mevinphos	methyl 3-mydroxycrotonate dimethyl phosphate (alpha-isomer)	Do.
Mobam*	benzo[b]thien-4-yl methylcarbamate	Carbamate.
Mocap*	0-ethyl S,S-dipropyl phosphorodithioate	Organophosphorus.
Monitor*	0,S-dimethyl phosphoramidothioate	Do.

Footnotes at end of table.

READILY DEGRADABLE INSECTICIDES (INCLUDING MITICIDES)—Continued

Common name (or trade name*)	Chemical name (or source)	Type of compound
Naled	1,2-dibromo-2,2-dichlorethyl dimethyl phosphate	Do.
Neo-pynamin*	2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylic acid ester with N-(hydroxymethyl)-1-cyclohexene-1,2-dicarboximide	Pyrethroid.
Nicotine	(principal active ingredient from Nicotiana tabacum)	Natural product.
Parathion	O,O-diethyl O-p-nitrophenyl phosphorothioate	Organophosphorus.
Phorate	O,O-diethyl S-[(ethylthio)methyl] phosphorodithioate	Do.
Phosphamidon	dimethyl phosphate ester with 2-chloro-N,N-diethyl-3-hydroxycrotonamide	Do.
Pyrethrins	(active insecticidal constituents of Chrysanthemum cinerariaefolium)	Natural product.
Rotenone	(principal active ingredient of derris and cube)	Do.
Ruelene*	4-tert-butyl-2-chlorophenyl methyl methylphosphoramidate	Organophosphorus.
Ryania	(powdered stemwood of Ryania speciosa)	Natural product.
Sabadilla	(alkaloid mixture isolated from seeds of Schoenocaulon officinale)	Do.
SBP-1382 (Penick)	(5-benzyl-3-furyl)methyl 2, 2-dimethyl-3-(2-methylpropenyl)=cyclopropanecarboxylate	Pyrethroid.
Schradan	octamethylpyrophosphoramide	Organophosphorus.
Sumithion*	O,O-dimethyl O-4-nitro-m-tolyl phosphorothioate	Do.
Trichlorfon	dimethyl (2, 2, 2-trichloro-1-hydroxyethyl) phosphonate	Do.

READILY DEGRADED, INACTIVATED, AND RELATIVELY NONPERSISTENT HERBICIDES[1]

Common name	Activity code	Chemical name	Type of compound
Acrolein	1	Acrolein	Acrylaldehyde.
Amitrole	1	3-amino-s-triazole	Triazole.
AMS	1	Ammonium sulfamate	Ammonium salt.
Atrazine	2	2-chloro-4(ethylamino)-6-(isopropylamino)-s-triazine	s-triazine.
Benefin	2	N-butyl-N-ethyl-alpha, alpha,alpha,-trifluoro-2,6-dinitro-p-toluidine	Aromatic amine.
Bromacil	3	5-bromo-3-sec-butyl-6-methyluracil	Uracil.
Ametryne	2	2-(ethylamino)-4-(isopropylamino)-6-(methylthio)-s-triazine	s-triazine.
Amiben	1	3-amino-2,5-dichlorobenzoic acid	Benzoic acid.
Atratone	2	2-(ethylamino)-4-(isopropylamino)-6-methoxy-s-triazine	s-triazine.
Barban	1	4-chloro-2-butynyl m-chlorocarbanilate	Carbamate.
CDAA	1	N,N-diallyl-2-chloroacetamide	Aliphatic amide.
CDEC	1	2-chloroallyl diethyldithiocarbamate	Carbamate.
Chloroxuron	2	3-[p-(p-chlorophenoxy)phenyl]-1,1-di-ethylurea	Urea.
Chlorpropham	1	isopropyl m-chlorocarbanilate	Carbamate.
2,4-D	1	(2,4-dichlorophenoxy) acetic acid	Phenoxy acid.
Dalapon	1	2,2-dichloropropionic acid	Aliphatic acid.
2,4-DB	1	4-(2,4-dichlorophenoxy)butyric acid	Phenoxy acid.
2,4-DEP	1	tris[2-(2,4-dichlorophenoxy)ethyl] phosphite	Phenoxy salt; organophosphorus.
Dicamba	2	3,6-dichloro-o-anisic acid	Benzoic acid.
Dichlobenil	3	2,6-dichlorobenzonitrile	Aromatic nitrile.
Dichlorprop	1	2-(2,4-dichlorophenoxy)propionic acid	Phenoxy acid.

Footnotes at end of table.

READILY DEGRADED, INACTIVATED, AND RELATIVELY NONPERSISTENT HERBICIDES[1] — Continued

Common name	Activity code	Chemical name	Type of compound
Diphenamid	2	N,N-dimethyl-2,2-diphenylacetamide	Araikyl amide.
Diquat	1	6,7-dihydrodipyrido[1,2-a:2′,1′-c]pyrazinedium salt	Heterocyclic quaternary salt.
EPTC	1	S-ethyl dipropylthiocarbamate	Carbamate.
Fenuron	2	1,1-dimethyl-3-phenylurea	Urea.
Fenuron TCA	2	1,1-dimethyl-3-phenylurea monotrichloroacetate	Do.
Ioxynil	1	4-hydroxy-3,5-diiodobenzonitrile	Aromatic nitrile.
Linuron	2	3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea	Urea.
MCPA	1	[(4-chloro-o-tolyl)oxy]acetic acid	Phenoxy acid.
Monuron	2	3-(p-chlorophenyl)-1,1-dimethylurea	Urea.
Norea	2	3-(hexahydro-4,7-methanoindan-5-yl)-1,1-dimethylurea	Do.
Paraquat	1	1,1′-dimethyl-4,4′-bipyridinium salt	Heterocyclic quaternary salt.
Prometone	2	2,4-bis(isopropylamino)-6-methoxy-s-triazine	s-triazine.
Prometryne	2	2,4-bis(isopropylamino)-6-(methylthio)-s-triazine	Do.
Propham	1	isopropyl carbanilate	Carbamate.
Pyrazon	1	5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone	Pyridazine.
Sesone	1	2-(2,4-dichlorophenoxy)ethyl sodium sulfate	Phenoxy salt.
			[P. 28992]
Simetone	2	2,4-bis(ethylamino)-6-methoxy-s-triazine	s-triazine.
Simetryne	2	2,4-bis(ethylamino)-6-(methylthio)-s-triazine	Do.
2,4,5-T	1	(2,4,5-trichlorophenoxy)acetic acid	Phenoxy acid.
TCA	1	Trichloroacetic acid	Aliphatic acid.
Trifluralin	2	α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine	Aromatic amine.
Metobromuron	2	3-(p-bromophenyl)-1-methoxy-1-methylurea	Urea.
Molinate	1	S-ethyl hexahydro-1-H-azepine-1-carbothioate	Carbothioate.
MSMA	2	Monosodium methanearsonate	Organoarsenical.
Naptalam	1	N-1-naphthylphthalamic acid	Phthalic acid.
Neburon	1	1-butyl-3-(3,4-dichlorophenyl)-1-methylurea	Urea.
Nitralin	2	4-(methylsulfonyl)-2,6-dinitro-N,N-dipropylaniline	Aromatic amine.
Nitrofen	1	2,4-dichlorophenyl p-nitrophenyl ether	Diphenyl ether.
PCP	1	Pentachlorophenol	Phenol.
Pebulate	1	S-propyl butylethylthiocarbamate	Carbamate.
Propachlor	1	2-chloro-N-isopropylacetanilide	Anilide.
Propanil	1	3′4′-dichloropropionanilide	Do.
Propazine	2	2-chloro-4,6-bis(isopropylamino)-s-triazine	s-triazine.
Siduron	2	1-(2-methylcyclohexyl)-3-phenylurea	Urea.
Silvex	1	2-(2,4,5-trichlorophenoxy)propionic acid	Phenoxy acid.
Simazine	2	2-chloro-4,6-bis(ethylamino)-s-triazine	s-triazine.
Swep	1	Methyl 3,4-dichlorocarbanilate	Carbamate.
TCA	1	Trichloroacetic acid	Aliphatic acid.
Terbacil	3	3-tert-butyl-5-chloro-6-methyluracil	Uracil.
Triallate	1	S-(2,3,3-trichloroallyl) diisopropylthiocarbamate	Carbamate.
Trietazine	2	2-chloro-4-(diethylamino)-6-(ethylamino)-s-triazine	s-triazine.
2,4-D	1	(2,4-dichlorophenoxy)acetic acid	Phenoxy acid.
2,4-DB	1	4-(2,4-dichlorophenoxy)butyric acid	Do.
2,4-DEB	1	2-(2,4-dichlorophenoxy)ethyl benzoate	Do.

Footnotes at end of table.

READILY DEGRADED, INACTIVATED, AND RELATIVELY NONPERSISTENT HERBICIDES[1]—Continued

Common name	Activity code	Chemical name	Type of compound
2,4,5-TES	1	Sodium 2-(2,4,5-trichlorophenoxy)ethyl sulfate	Phenoxy acid, salt.
Vernolate	1	S-propyl dipropylthiocarbamate	Carbamate.
Bromoxynil	1	3,5-dibromo-4-hydroxybenzonitrile	Aromatic nitrile.
Butylate	1	S-ethyl diisobutylthiocarbamate	Carbamate
CDEA	1	2-chloro-N,N-diethylacetamide	Aliphatic amide.
Chlorazine	2	2-chloro-4,6-bis(diethylamino)-s-triazine	s-triazine.
Cycloate	1	S-ethyl N-ethylthiocyclohexanecarbamate	Carbamate.
Cycluron	2	3-cyclooctyl-1,1-dimethylurea	Urea.
DCPA	1	Dimethyl tetrachloroterephthalate	Phthalic acid.
Diallate	1	S-(2,3-dichloroallyl) diisopropylthiocarbamate	Carbamate.
Dinosam	1	2-(1-methylbutyl)-4,6-dinitrophenol	Nitrophenol.
Dinoseb	1	2-sec-butyl-4,6-dinitrophenol	Do.
Diuron	2	3-(3,4-dichlorophenyl)-1,1-dimethylurea	Urea.
DNOC	1	4,6-dinitro-o-cresol	Nitrophenol.
DSMA	2	Disodium methanearsonate	Organoarsenical.
Endothall	1	7-oxabicycle (2.2.1)heptane-2,3-dicarboxylic acid	Phthalic acid.
Erbon	1	2-(2,4,5-trichlorophenoxy)ethyl 2,2-dichloropropionate	Phenoxy acid.
Fenac	3	(2,3,6-trichlorophenyl)acetic acid	Do.
Fluometuron	2	1,1-dimethyl-3-(a, a, a,-trifluoro-m-tolyl)urea	Urea
HCA	1	1,1,1,3,3,3-hexachloro-2-propanome	Hexachloroacetane.
Ipazine	2	2-chloro-4-(diethylamino)-6-(isopropylamino)-s-trazine	s-triazine.
Isocil	3	5-bromo-3-isopropyl-6-methyluracil	Uracil.
KOGN	1	Potassium cyanate	Cyanate.
MCPB	1	4-[(4-chloro-o-tolyl)oxy]butyric acid	Phenoxy acid.
MCPES	1	2-[(4-chloro-o-tolyl)oxy]ethyl sodium sulfate	Do.
Metham	1	Sodium methyldithiocarbamate	Carbamate.

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[1] Herbicides whose degradation, inactivation, and persistent characteristics are such that their use, in accordance with treatments registered for selective control of weeds on cropland, pose no significant problem with respect to registered tolerances for herbicide residues or crop production in following seasons. This list is not all inclusive, particularly with respect to new materials. The herbicides listed are coded as to their degradability, persistence, and inactivation in soil. The legend for the code numbers is as follows:

1. Compounds normally degraded or inactivated, and usually do not persist more than 12 months.
2. Compounds that may persist for more than 12 months, but are normally degraded or inactivated in less than 24 months.
3. Compounds that may persist for more than 24 months, but are normally degraded or inactivated, and usually do not persist for more than 48 months.

READILY DEGRADED, RELATIVELY NONPERSISTENT FUNGICIDES

Common name (or trade name*)	Chemical name	Type of compound
Captan	N-[(trichloromethyl)thio]-4-cyclohexene-1,2-dicarboximide	Chlorothiocarboximide.
Chloranil	2,3,5,6-tetrachloro-p-benzoquinone	Chlorinated quinone.
Chloroneb	1,4-dichloro-2,5-dimethoxybenzene	Chlorinated aromatic ether.
Daconil 2787*	2,4,5,6-tetrachloroisophthalonitrile	Chlorinated aromatic nitrile.
DCNA	2,6-dichloro-4-nitroaniline	Chlorinated aniline.
Dichlone	2,3-dichloro-1,4-napthoquinone	Chlorinated quinone.
Difolatan*	cis-N-[(1,1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide	Chlorothiocarboximide.
Dinocap	2-(1-methylheptyl)-4,6-dinitrophenyl crotonate	Dinitrophenyl ester.
Dodine	Dodecylguanidine acetate	Alkyl guanidine salt.
Dyrene*	2,4-dichloro-6-(o-chloroanilino)-s-triazine	Chlorinated triazine.
Ethoxyquin	6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline	Ethoxyquinoline.
Ferbam	Ferric dimethyldithiocarbamate	Ferric thiocarbamate.
Folpet	N-[(trichloromethyl)thio]phthalimide	Chlorothiocarboximide.
Glyodin	2-heptadecyl-2-imidazoline acetate	Alkyl imidazoline salt.
Lanstan*	1-chloro-2-nitropropane	Chloronitroalkane.
Lime sulfur	30% calcium polysulfide and various small amounts of calcium thiosulfate plus water and free sulfur	Calcium polysulfides.
Maneb	Manganese ethylenebis [dithiocarbamate]	Manganese thiocarbamate.
Morestan*	6-methyl-2,3-quinoxalinedithiol cyclic S,S-dithiocarbonate	Thioquinoxaline.
Nabam	Disodium ethylenebis [dithiocarbamate]	Sodium thiocarbamate.
Niacide*	Mixture of manganese dimethyldithiocarbamate and 2-benzothiazolethiol	Manganese thiocarbamate.
Pipron*	3-(2-methylpiperidino) propyl 3,4-dichlorobenzoate	Chlorinated piperidyl benzoate.
8-quinolinol	8-quinolinol	Hydroxyquinoline.
Sulfur	Sulfur	Elemental sulfur.
Thioquinox	2,3-quinoxalinedithiol cyclic trithiocarbonate	Thioquinoxaline.
Thiram	Bis (dimethylthiocarbamoyl) disulfide	Thiocarbamate.
Tricamba	3,5,6-trichloro-o-anisic acid	Chlorinated benzoic acid.
Zineb	Zinc ethylenebis (dithiocarbamate]	Zinc thiocarbamate.
Ziram	Zinc dimethyldithiocarbamate	Do.
Mertect*	2-(4-thiazolyl) benzimidazole	Thiabendazole.
Polyram*	Mixture of 5.2 parts by weight of ammoniate of [ethylenebis(dithiocarbamato)] zinc with 1 part by weight ethylenebis[dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides	Dithiocarbamate.
Streptomycin	2,4-diguanidino-3,5,6-trihydroxycyclohexyl 5-deoxy-2-O-(2-deoxy-2-methylamino-a-glucopyranosyl)-3-formyl pentofuranoside	Antibiotic (produced by Streptomyces griseus).
Vitavax*	2,3-dihydro-5-carboxanilido-6-methyl-1,4-oxathiin	1,4-oxathiin derivative.

[P. 28993]

READILY DEGRADABLE, RELATIVELY NONPERSISTENT NEMATICIDES

Common name (or trade name*)	Chemical name (or source)	Type of compound
EDB	1,2-dibromoethane	Hydrocarbon.
DBCP	1,2-dibromo-3-chloropropane	Do.
DD	1,3-dichloropropene and 1,2 dichloropropane	Do.
Methyl bromide	Monobromomethane	Do.
Chloropicrin	Trichloronitromethane	Do.
Penphene*	2,3,4,5-tetrachlorothiophene	Do.
Dazomet	3,5-dimethyltetrahydro-1,3,5,2H	Carbamate.
Aldicarb	2-methyl-2-(methylthio) propionaldehyde O-(methylcarbamoyl) oxime	Do.
Methomyl	S-methyl N-(methylcarbamoyl)oxy)thioacetimidate	Do.
Metham-sodium	Sodium N-methyldithiocarbamate	Do.
Parathion	O,O-diethyl O-p-nitrophenyl phosphorothioate	Organophorus.
MENCS	Methyl isothiocyanate	Do.
Mocap*	O-ethyl S,S-dipropyl phosphorodithioate	Do.
Desanit*	O,O-diethyl O-p-(methylsulfinyl)phenyl phosphorothioate	Do.
Bay 68138	Ethyl 4-(methylthio)-m-toyl isopropylphoramidate	Do.
Thionazin	O,O-diethyl O-2-pyrazinyl phosphorothioate	Do.
Diazinon	O,O-diethyl O-(2-isopropyl-4-methyl-6-pyrimidinyl) phosphorothioate	Do.
Carbofuran	2,3-dihydro-2,2-dimethyl-7-benzofuranyl methyl-carbamate	Do.
V-C 13 Nemacide*	O-(2,4-dichlorophenyl) O,O-diethyl phosphorothioate	Do.

Mr. NELSON. Mr. President, fourth, is the increased use of systems of integrated pest control, combining biological and chemical controls, and additionally, developing pest-resistant crop strains. This approach is showing increased success as an effective economic means of pest control;

Fifth, further development of agents which cause the persistent pesticides to decompose more rapidly in the soil and water after they have been applied to a crop and accomplished their task; and,

Sixth, the development of standards on the biodegradability and toxicity of pesticide components.

COMPREHENSIVE STUDY

Part 2 of the amendment directs the Secretary of the Interior, in consultation with appropriate Federal agencies, and other concerned parties, to conduct a study on methods of controlling the release of pesticides in our Nation's lakes and rivers and the environment. The study will include examination of the persistency of pesticides in the water and alternatives thereto. Within the 2 years, the Secretary will submit a report on this study to Congress together with his recommendations for any necessary legislation.

This study should assist the Secretary in perfecting existing means of dealing with pesticide pollution and in determining new ones, to assure equitable and enforceable standards.

There is abundant evidence to show that the six approaches—State action, interstate action, integrated pest control, use of less persistent pesticides, development of agents to decompose pesticides, and biodegradability and toxicity standards—will prove effective in the nationwide program of pesticide water quality criteria and standards which this amendment would establish.

For instance, a report published this month by the American Chemical Society described in detail a number of means by which the massive pesticide contamination can be minimized. I believe it would be helpful to outline some of the information provided by this and other reports which we have studied.

First, since pesticides have been billed as a panacea for controlling all pests, heavy application has become a national habit, whether it is needed or not. For example, cotton is often sprayed with toxic, persistent pesticides every 5, 7, or 10 days.

BETTER PESTICIDE USE

Yet, with effective use of our improved knowledge of the life cycle and behavior of both the crop and the pest, pesticide application could be cut down to only that period of the time when a pest is in fact endangering a crop.

In addition, acceptance of the valid idea that 100-percent pest control need not be achieved would further cut pesticide use. Often, damage to crop production could be prevented with just a 75-percent control of the pests.

Another valid application method which would further cut pesticide use, expense, and pollution, is treating only the areas that are heavily infested with pests. As an example, mountain water in North Carolina was found to contain more than 0.3 part per billion of DDT when an entire oak-hickory forest was treated for a tree disease. Later, when only the region of the forest affected by the disease was treated, it was impossible to find any trace of DDT in the waters. And the disease was still controlled.

If improved application equipment were used, there would be another significant reduction in pesticide use.

A Mississippi study on the aerial application of the persistent pesticide heptachlor showed that only 17 percent of the compound was applied at the proper rate on the crop. The remainder either missed the crop, was applied at a rate much lower than necessary, or was applied at a rate much higher than necessary. In another study, only 10 to 20 percent of a pesticide dust reached the plant, with the remainder missing its target entirely.

Concentrated efforts to eradicate whole pests populations also offer great promise. For example, if just three pests, the boll weevil, the boll worm, and the codling moth, were eradicated, it would be possible to reduce the amount of insecticides applied each year in the United States by some 40 percent.

BIOLOGICAL CONTROL

Insect sterilization has become one of the most effective ways to eliminate a total insect population. This was the technique that was used to eradicate the screw-worm fly from the Southeast United States. The U.S. Department of Agriculture raised millions of screw-worm flies weekly, with radioactive cobalt used to make the flies reproductively sterile.

Massive numbers of sterilized flies were air dropped regularly over thousands of square miles infested by native screw-worm flies. The sterile flies mated with the native females, and the resulting eggs failed to hatch. Repeated releases of sterile flies reduced screw-worm numbers, until the pests finally disappeared.

Presently, the Agriculture Department is maintaining a barrier zone along the United States-Mexico border to keep out new screwworms though continuously releasing sterile flies along that area.

The American Chemical Society says that the ideal pesticide should be as effective as possible against one or several pests and as safe as possible to all other forms of life, including beneficial insects and predators, fish and other wildlife, domestic animals, and man. As one of its main recommendations in its recent report, the Society urged:

> Persistent pesticides should only be used in minimal amounts and under conditions where they have been shown not to cause widespread contamination of the environment. Where possible, highly persistent materials should be replaced by rapidly degradable materials.

The feasibility of this approach is demonstrated by the fact that, as pointed out earlier, for virtually all crops, there are several pesticides, some very persistent and some not, which can effectively control harmful pests.

In several parts of the country, the cost of pesticide use has increased so drastically, that other systems of pest control with little or no reliance on chemical formulations have been adopted with great success.

INTEGRATED PEST CONTROL

Among these approaches is integrated pest control, which can be best defined as an insect population management system that depends primarily on the use of beneficial predator insects with limited reliance on the use of selective chemicals.

Presently there are successful integrated pest control programs in operation on the following crops: cotton, citrus fruits, apples and pears, tomatoes, potatoes, avocadoes, olives, grapes, corn, eggplant, lettuce, strawberries and others.

This means of pest control is based on the principles of applied ecology. In order for success to be achieved, the fields must be placed under periodic surveillance to determine when and where specific pest infestations occur. When a problem is discovered, predators [p. 28994], parasites, or disease organisms specifically related to that pest are released to bring the pests back into a favorable balance. Very limited amounts of pesticide may be used, but only when absolutely necessary, and only on the infested area of the crop.

While many farmers and other pesticide users resist giving up chemical means of pest control because they feel that other alternatives may be more costly, the opposite has been proven true with regard to integrated pest control.

LOWER COST

Prof. Robert VandenBosch of the College of Agricultural Sciences, University of California at Berkeley, cites this example: The cost of pest control using chemical pesticides for 4,000 acres of cotton in California was $185,000. When integrated pest control replaced the use of chemical pesticides, the cost dropped to $20,000 a year. The statistics for spotted alfalfa in California are very similar, where in 1957, the cost of pest control with chemical pesticides was at least $12 million. Today, after the introduction of integrated pest control, the cost has been reduced to only $3 million, with little or no pest problems remaining.

A recent edition of the Western Fruit Grower cites additional cases of the successful and economical application of integrated pest control in place of the use of chemical pesticides. One expert in biological control has enabled a producer of Valencia oranges to reduce the cost of pest control from $200 per acre, using chemical control, to only $60 an acre with integrated pest control. Another orange grower has been able to reduce his cost per acre for pest control to just $35 per acre, using integrated pest control, and has had higher yields than ever in the history of the grove.

Another pest control approach showing major promise is the use of hormones. The principle is to give an insect its own hormone at the wrong stage of its life, so that it upsets the bug's growth processes and causes it to destroy itself.

Finally, the search is now underway for a catalyst which would cause DDT to self-destruct after it had accomplished its insect control tasks. If successful, this would be a major breakthrough in dealing with the tendency of hard pesticides to persist in the environment long after they are needed. Secretary of the Interior Walter Hickel recently announced the award of a contract to test this approach.

America and the world cannot afford to wait much longer to decide that hurling the crude weapon of hard pesticides against the fabric of life, the apt description by Rachel Carson, is not the answer to our pest control problems.

Our approach must be much more sophisticated than that, and as I have outlined above, there is an abundance of alternatives. And there is no reason why the job cannot be done more effectively and far more economically than the present massive, indiscriminate pesticide use. The savings would accrue to the farmer and all other pesticides users, to our environment, and most importantly, to future generations of life on earth.

I believe the pesticide amendment to S. 7 is a major step in the right direction. Criteria would be developed, standards would be set and implemented, and the means to meet these standards brought into use.

I urge the Senate's adoption of the amendment, and I am heartened and deeply appreciative of the cosponsorship of this proposal by 31 Senators, including the chairman of the Senate Public Works Committee, Senator RANDOLPH, and the chairman of the Subcommittee on Air and Water Pollution, Senator MUSKIE, who is the author of S. 7.

This board support is without question a confirmation of the growing insistence of Congress that the quality of the American environment and the quality of life for all Americans be given the protection that is so urgently needed.

EXHIBIT 1

U.S. DEPARTMENT OF THE INTERIOR
FEDERAL WATER POLLUTION CONTROL ADMINISTRATION
Washington, D.C., August 25, 1969.

HON. GAYLORD NELSON,
U.S. Senate,
Washington, D.C.

DEAR SENATOR NELSON: In accordance with Mr. John Heritage's recent request by telephone to Mr. Bern Wright of our Water Quality Standards Branch, a review has been made of the States' water quality standards requirements on pesticides and the following information and enclosed summaries are being provided for your use.

Most of the State standards contain one or more requirements by which limits on specific toxic substances may be imposed on a case-by-case basis. These controls are found in the standards in the form of a general narrative statement on toxicity, or they may be included in the public water supply or aquatic life use criteria. Three of the States have specific numerical limits for pesticides and at least two others specifically mention pesticides in their toxicity standards.

SPECIFIC NUMERICAL STANDARDS ON PESTICIDES

Alaska

Standards of the State of Alaska contain a pesticide limit of 0.001 of the 96-hour LC_{50}. (96-hour LC_{50} means the lethal concentration of a substance that will result in a 50% kill of the test organism in a 96-hour period.)

California

Tidal Waters Inland from the Golden Gate within the San Francisco Bay Region — No individual pesticide or combination of pesticides shall reach concentrations found to be deleterious to fish or wildlife at any place.

Goose Lake — The total chlorinated hydrocarbon pesticide content shall not exceed 0.10 micrograms per liter as determined by the summation of the individual concentrations, and the individual pesticide content shall not reach those levels found to be detrimental to aquatic life and wildlife.

Idaho

Toxic or Other Deleterious Substances (pesticides, phenolics and related organic and inorganic materials)—Toxic chemicals of other than natural origin in concentrations found to be of public health significance or adversely affect the uses indicated. Guides such as the Water Quality Criteria published by the State of California Water Quality Control Board, Second Edition, 1963, will be used in evaluating the tolerances of the various toxic chemicals for the use indicated.

South Dakota

Pesticides, herbicides and related compounds shall be treated as toxic materials and taste and odor producing chemicals and controlled under the provisions of Chapter II, Section II, Subsection 2 and 4.

Chapter II, Section II, Subsection 2—*Toxic Materials.* No materials shall be discharged to any surface water or watercourse in the State which produce concentrations of chemicals toxic to humans, animals or the most sensitive stage or form of aquatic life greater than 0.1 times the acute (96-hour) median lethal dose for short residual compounds or 0.01 times the acute median lethal dose for accumulative substances or substances exhibiting a residual life exceeding 30 days in the receiving waters.

Chapter II, Section II, Subsection 4—*Taste and Odor Producing Chemicals.* No materials shall be discharged which will result in concentrations in the receiving water sufficient to impart objectionable tastes and odors to edible aquatic life.

Virginia

Salt water (shellfish)—Area is not to be so contaminated with radionuclides, pesticides, herbicides or fecal material, that consumption of the shellfish might be hazardous.

PUBLIC WATER SUPPLY CRITERIA

Several States have included the Public Health Service (PHS) Drinking Water Standards as requirements for establishing the quality of water to be maintained as an acceptable source of public water supply. These standards establish a limit of 0.2 mg/1 for Carbon Chloroform Extract (CCE). This is intended to be a general safety control for the detection of "ill defined" chemicals which could include pesticides. The CCE control is not intended for replacement of specific limits on pesticides and other toxic substances.

Those States which expressly include the PHS requirements for waters designated for public water supply use are as follows: Alabama, Alaska, California, Connecticut, Georgia, Maine, Michigan, Minnesota, Montana, Nebraska, North Carolina, Rhode Island, Vermont, West Virginia, Wyoming.

AQUATIC LIFE-TOXICITY STANDARDS

All of the States' standards provide for the protection of aquatic life from toxic substances. Appendix A is a summary of these requirements as they relate to aquatic life.

A copy of the "Report of the Committee on Water Quality Criteria—Federal Water Pollution Control Administration" is also enclosed for your reference use. Pages 56, 58, 59 of this report provide discussions on "Toxic Substances" and "Bioassay" which may be helpful to you in interpreting the standards on toxic substances. You will also find on pages 62-65, 82-83, 116, 118, 131, 137, 156 of this report information on pesticides. Each of the

State water pollution control agencies have been provided a copy of this report and it is being widely used by the States as a guide in the updating of their water quality standards.

If you have any further questions concerning specific requirements in the standards, please let me know.

Sincerely yours,

DAVID D. DOMINICK,
Commissioner.

APPENDIX A—*TOXICITY STANDARDS For Surface Waters Used for FISH PROPAGATION AND WILDLIFE*

(Toxic substances—Maximum allowable (mg/1))

Alabama: Only amounts not injurious to fish and aquatic life, including shrimp and crabs, or the propagation thereof. 1/10 of 48-hour TL_m or other approved limits.

Alaska: Less than acute or chronic problem levels as revealed by bioassay. None which causes tainting of flesh of edible species.[b] Pesticides: 0.001 of 96-hour LC_{50}[b].

Arizona: Biocide concentrations shall be [p. 28995] kept below levels which are deleterious to human, animal, plant, or aquatic life, or in amounts which interfere with this use.

Arkansas: Shall not be present in quantities toxic to human, animal, plant, or aquatic life or which interfere with the normal propagation of aquatic life. 1/10 of 48-hour TL_m.

California: At all times less than the concentrations toxic or harmful to wild or domestic animals or to aquatic life.

Colorado: Free from biocides, toxic, or other deleterious wastes in concentrations or combinations sufficient to be harmful to aquatic life.

Connecticut: Free from chemical constituents in concentrations or combinations which would be harmful to human, animal, or aquatic life. Bioassays shall be performed as needed.

Delaware: None in concentrations harmful (synergistically or otherwise) to humans, fish, wildlife, and aquatic life.

District of Columbia: None from waste sources in concentrations or combinations which are harmful to human, animal, plant, or aquatic life or which interfere with this use.

Florida: Free from waste substances toxic or harmful to human, animal, or aquatic life. F: 10.0 Cu–0.5, Zn–1.0, Cr^6–0.05, Pb–0.05, Fe–0.3, As–0.05. Cn: none detectable.

Georgia: None in concentrations that would harm man, fish and game, or other beneficial aquatic life.

Territory of Guam: Free from waste materials that will be toxic or irritating to humans, animals, plants, or aquatic life.

Hawaii: Free from biocides, toxic, or other deleterious substances in concentrations harmful to human, animal, or marine life, or which cause unpleasant taste in seafood.

Idaho: No toxic chemicals of other than natural origin, in concentrations of public health significance or which adversely affect this use.

Illinois: 1/10 of 48-hour TL_m, As–1.0, Ba–5.0 Cd–0.05, Cr^6–0.05, Cr^3–1.00, Cu–0.04, Cn–0.025, Pb–0.1, Ag–0.05, An–1.00.

Indiana: 1/10 of 96-hour TL_m from continuous-flow bioassays where the dilution water and toxicant are continuously renewed, or other factors when justified and approved.

Iowa: NH_3–2.0, As–1.0, Ba–5.0, Cd–0.05, Cr^6–0.05, Cr^3–1.00, Cu–0.02, Cn–0.025, Pb–0.10, Zn–1.0. Maximum of 5.0 for entire heavy metal group.

Kansas: Pollutional substances will be maintained below maximum permissible concentrations which would be detrimental for recreational requirements.

Kentucky: 1/10 of 48-hour TL_m. Free from waste substances in concentrations or combinations which are toxic or harmful to human, animal, plant, or aquatic life.

Louisiana: 1/10 of 48-hour TL_m. None present in quantities that alone or in combination will be toxic to animal or plant life.

Maine: No chemical constituents from waste sources, which are harmful to humans, animal, or aquatic life, or which adversely affect this use.

Maryland: Free from toxic wastes which interfere with this use or which are harmful to human, animal, plant or aquatic life.

Massachusetts: None at levels harmful to human, animal, or aquatic life, or which make the waters unsuitable for fish or their propagation, or impair their palatability.

Michigan: 1/10 of 96-hour TL_m, from continuous flow bioassays.

Minnesota: Cr–tr, Cu–tr, Cn–tr, $NH_3(N)$–trbl, Cr–1.0, Cu–0.2, Cn–0.02, $NH_3(N)$–1.0[c], Cr–1.0, Cu–0.2, Cn–0.02, $NH_3(N)$–2.0[d]. None directly or indirectly harmful.[e]

Mississippi: 1/10 of 48-hour TL_m.

Missouri: None which have harmful effect on human or animal life.

Montana: 1/10 or 96-hour TL_m for short residual materials and 1/100 of 96-hour TL_m for pesticides.

Nebraska: None in combinations or concentrations which render the water unsafe or unsuitable for this use.

Nevada: None present in concentrations, from other than natural origin, which are deleterious to animal, plant, or aquatic life, or which exceed the 1962 PHS "Drinking Water Standards."

New Hampshire: None in toxic concentrations or combinations. Free from chemicals and conditions inimical to fish or the maintenance thereof.

New Jersey: None which would affect hu-

Footnotes at end of article.

mans or be detrimental to the natural aquatic biota.

New Mexico: 1/10 of 48-hour TL_m. Shall not change the ecology to an extent detrimental to existing forms of life nor be toxic to humans, plants, fish, or animals.

New York: None alone or in combination with other substances or wastes in sufficient amounts to be injurious to fish life or impair the water for this use.

North Carolina: 1/10 of 48-hour TL_m. Shall not change the ecology to an extent detrimental to existing forms of life nor be toxic to humans, plants, fish, animals.

North Dakota: No waste materials, either in concentrations or combinations, which result in the waters being toxic or harmful to human, animal, or aquatic life.

Ohio: 1/10 of 48-hour TL_m. Free from waste substances in concentrations or combinations which are toxic or harmful to human, animal, or aquatic life.

Oklahoma: 1/10 of 48-hour TL_m. Shall not be present in such quantities as to cause the waters to be toxic to human, animal, plant, or aquatic life.

Oregon: No conditions deleterious to fish or other aquatic life or which affect the palatability of fish.

Pennsylvania: None in amounts sufficient to be inimical or harmful to this use.

Commonwealth of Puerto Rico: None alone or in combination with other substances or wastes in amounts injurious to edible fish or their culture, taste, or propagation.

Rhode Island: Bioassays shall be performed as required by the appropriate agencies. None which would be harmful to human, animal, or aquatic life.

South Carolina: Free from waste materials which are toxic or harmful to human, animal, plant, or aquatic life, or which interfere directly or indirectly with this use.

South Dakota: 1/10 of 96-hour TL_m for short residual compounds. 1/100 of 96-hour TL_m for substances of residual life exceeding 30 days. Cn–02[d1e1fg] 0.05[h].

Tennessee: There shall be no substances added that will produce toxic conditions that affect fish or aquatic life.

Texas: Shall not exhibit acute or chronic toxicity to human, animal, or aquatic life to such an extent as to interfere with this use.

Utah: No waste materials in concentrations or combinations which are toxic or which produce undesirable physiological responses in humans, fish, and other animal life, and plants.

Vermont: Bioassays shall be performed, including assessment of taste and odor. Free from chemical constituents harmful to human, animal, or aquatic life.

Virginia: Free from toxic substances attributable to waste, in concentrations or combinations which interfere directly or indirectly with this use.

Virgin Islands of the United States: Free from waste substances in concentrations or combinations which are toxic or harmful to human, animal, or aquatic life.

Washington: Below concentrations which may cause acute or chronic toxic conditions to the aquatic biota.

West Virginia: No concentrations of materials poisonous to man, animal, or fish life.

Wisconsin: None present in amounts which by bioassay or other tests indicate acute or chronic levels harmful to animal, plant, or aquatic life.

Wyoming: Free from toxic substances of other than natural origin in concentrations or combinations which are toxic to human, animal, or aquatic life.

FOOTNOTES

[b] Standard reserved from approval by FWPCA.

[b1] Applies to propagation and maintenance of warm and coldwater sport or commercial fishes.

[b2] Standards apply only to coastal waters.

[c] Applies to propagation and maintenance of sport and commercial fishes.

[d] Applies to propagation and maintenance of fish species common to the area waters.

[d1] Fish life propagation—coldwater permanent.

[e] Applies to use by wildlife.

[e1] Fish life propagation—coldwater marginal.

[f] Fish life propagation—warmwater permanent.

[g] Fish life propagation—warmwater semipermanent.

[h] Fish life propagation—warmwater marginal.

Mr. RANDOLPH. Mr. President, will the Senator yield?

Mr. NELSON. I yield to the Senator from West Virginia.

Mr. RANDOLPH. Mr. President, the Senator from Wisconsin has often appeared before the Committee on Public Works and its subcommittees in reference to the matters of cleansing the air and purifying the water. I will not mention the long list of affirmative actions he has initiated in the Senate. I am not sure how many cosponsors on the amendment, but I do know there is a considerable list. I am delighted I could join him in the amendment.

In the joining with him we recognize his leadership in this field. I think his explanation this afternoon of the presence of pesticides and the danger that can be wrought by this type pollution is a real one. I express my thanks for his constructive efforts.

Mr. NELSON. I thank the distinguished chairman of the Committee on Public Works for his gracious remarks. I might add, however, the reason I appeared before the Committee on Public Works, of which the Senator from West Virginia is chairman, is that that committee has been doing such extensive work in the field of enhancing the quality of air and water in this country. They have made it possible for conservationists and Members of Congress to appear in connection with legislation of this nature to which his committee has devoted so much time.

Mr. MONDALE. Mr. President, I rise in support of the amendment (No. 132) introduced by the Senator from Wisconsin (Mr. NELSON) to S. 7.

I have already stated the many reasons that I support the Water Quality Improvement Act of 1969, and I appreciate this opportunity to direct specific remarks to the amendment now proposed by my distinguished colleague from Wisconsin.

Under the proposed amendment, the Secretary of the Interior is directed to take certain steps that would guarantee water quality criteria for all pesticides. The criteria would be based on the effects of various pesticide levels on fish and wildlife, as well as man and his environment. The criteria would outline maximum safe levels for the presence of pesticides in water, and these would represent the essential basis for State or Federal action [p. 28996] to deal with the pesticide pollution problem.

It is clear that persistent pesticides are so polluting our rivers, lakes, streams, and oceans that fish can and have been killed; that fish reproduction can and has been inhibited; that high pesticide residues in water have affected birds and other animals; and, that now, even man is threatened.

Specifically, the amendment would permit the Secretary of the Interior, after consultation with all interested and concerned parties, to prepare and publish regulations setting forth water quality standards for pesticides that will clearly not have a deleterious effect on fish or man. Responsibility for enforcing the standards would rest primarily with the States. Standards could be implemented by issuing orders to polluters to take remedial measures.

A particularly significant aspect of this amendment is that it permits the establishment of a system for tabulating, monitoring, and recording precisely what pesticide residues should be permitted.

As chairman of the Senate Subcommittee on Migratory Labor, I have become particularly aware of the need to establish similar procedures insofar as farmworkers may be affected by pesticide use.

There is mounting evidence concerning the harmful effects of pesticides on our Nation's migrant and seasonal farmworkers. Experts from the Department of Health, Education, and Welfare concede that perhaps as many as 800 farmworkers are killed and 80,000 injured by pesticides each year. We know that the agricultural industry experiences one of the highest occupational disease rates in the United States. Just last week we learned that a substantial proportion of farmworkers experience symptoms of chemical poisoning which include dermatitis, rashes, eye irritation, nausea, vomiting, fatigue, excess sweating, headaches, double vision, dizziness, skin irritations, difficulty in breathing, loss of fingernails, nervousness, insomnia, bleeding noses, and diarrhea.

It is clear from our hearings that proper safeguards and protections for farmworkers do not exist in the use of pesticides. In fact, under the present State and Federal regulations, information about how, when, and where chemicals are used is seldom available to the farmworker or to the public.

The hearing record is painfully lacking in any firm evidence that the pesticides to which farmworkers are daily exposed in fact have no deleterious short- or long-range effects on their health and well-being. Further, it was shocking to learn of the pitifully inadequate funding of programs devoted to research on occupational hazards to farmworkers; and to discover that programs aimed at protecting the farmworkers are neither adequately funded nor enforced.

We do know, however, from recent accounts in medical and scientific journals, that the wrong kinds of chemicals, in the wrong amounts, and in the wrong places are sometimes used with inadequate regard of the health and safety of their workers. Furthermore, we know that recent scientific investigations have produced evidence that DDT causes cancer in animals and provides very strong indications that DDT may produce cancer in man.

Mr. President, I support this amendment, because it establishes a mechanism for the Secretary of the Interior to determine maximum safe levels of pesticides in water that would represent the essential basis for action to deal with the pesticide pollution problem in water. Additionally, enactment of this amendment may serve as a workable model for necessary legislation to protect farmworkers through establishment of a meaningful system for monitoring pesticide effects on man.

Mr. MUSKIE. Mr. President, the amendment offered by the Senator from Wisconsin (Mr. NELSON) is a constructive addition to the legislation which is pending before the Senate. I have discussed this proposal with the Senator from Wisconsin and agree with the need to provide the Secretary of the Interior with a specific directive to formulate criteria which indicate the effects of pesticides on the water environment.

There is a growing national concern regarding the use of pesticides. Conservationists, scientists, medical experts, and ecologists are speaking out against indiscriminate use of pesticides while other scientists, health officials, and agricultural experts oppose actions to limit their availability and use.

Existing information is sufficient to suggest that we have not exercised due care in either the amount or type of pesticides we use. Inadequate attention has been paid to developing less toxic more degradable pesticides and thus, today, we are confronted with the potential of banning entirely the use of some materials which have been extremely helpful in expanding the Nation's productivity and protecting the Nation's health.

I am not prepared, at this time, to suggest that all pesticides, herbicides, fungicides, and insecticides should be banned or even that some of them should be banned. I support Senator NELSON'S amendment because we need to know a great deal more about the health and welfare effects of these pollutants and because existing scientific information needs to be assembled and evaluated.

The criteria to be published by the Secretary should provide useful assistance to the States in determining the extent to which the use of pesticides and water quality requirements are in conflict.

In some States it may be necessary to establish limitations on the availability of certain types of pesticides and, in other cases, it may be necessary to limit use of specific pesticides in certain watersheds. Whatever course is taken in controlling use of persistent pesticides, care should be taken to assure the public health responsibilities such as malaria control are not hindered.

Enforcement procedures must consider the differences between point source control available to municipal and industrial wastes as opposed to the general diffusion of the pollutant in this case. The inability to effectively control this type of pollutant after application suggests the need to consider legislation which will establish uniform standards on the biogradability and toxicity of pesticides to assure environmental protection prior to the indiscriminate introduction of pesticides into the environment.

The Senator from Wisconsin (Mr. NELSON) has indicated an intent to introduce such legislation in the near future. I will cosponsor his proposal and the Subcommittee on Air and Water Pollution will hold hearings early next year.

I would like to ask the distinguished Senator this question. First of all I share the Senator's concern about the growing dilemma of pesticide pollution. In many ways I think it is perhaps the most serious in its potential impact upon the environment, upon wildlife, and upon human life itself. It is the most persistent and most difficult to come to grips with once pesticides are released in the environment. In that sense, it is like air pollution. Once discharged, it cannot be controlled; so, as in the case of pesticides at the dispersal point.

Since the problem of control is, for that reason, somewhat different from that of air pollutants, the enforcement problem is different in the same way. So we have to come to grips with that problem.

The amendment offered by the distinguished Senator from Wisconsin is a major advance, I think, toward restoring and preserving the quality of our waters that are now threatened by pesticides.

In addition to leading to specific standards for safe concentrations of pesticides in interstate rivers and lakes, I believe that the amendment serves an equally important purpose of establishing a comprehensive program for research in the Department of the Interior, to study the problems of persistent pesticides and alternatives that can eliminate this contamination of our environment.

That is the point which, I think, is at the heart of resistance to the control of pesticides.

I ask the Senator from Wisconsin whether he believes that the standards that would be developed as a result of his amendment can be met without hindering efforts to control insects, weeds, fungus, and other pests that can cause damage to farmers and can pose a potential hazard to human health.

Mr. NELSON. I do not think there is any question about that. No Member of Congress is more familiar with the Water Pollution Control Act than the Senator from Maine (Mr. MUSKIE) who conducted the hearings, drafted the bill, and engineered its passage in the Senate.

As the Senator knows, under section 10(c) the Secretary can establish criteria, but he must consider the practicability and the economic feasibility of any standards that are proposed to be used. He must take these factors into consideration.

I make one other point. The Department of Agriculture prescribes an alternative pesticide for every chlorinated hydrocarbon, so far as I can ascertain, that is listed for use on virtually every crop in this country. In other words, there is another, more readily degrading pesticide that is readily available. As I review the application rates recommended by the [p. 28997] Department and the current prices of pesticides, the cost of hard pesticides compared with readily degradable pesticides is roughly the same.

I believe that the Senator knows Michigan and Arizona have already banned the use of DDT. My own State of Wisconsin is moving to drastically improve the controls on it and has created a board to determine if it is necessary to use certain pesticides. There is integrated pest control which has been initiated successfully in California in which they do not indiscriminately spray the crop. They use whatever biological methods they can, including certain organisms which prey on insects. But whatever method they use, biological or chemical, it is limited to the area where the pest is.

In my earlier remarks, I outlined those programs and the cost per acre, which is dramatically less for a program of integrated pest control. Unfortunately, so many people just hire an airplane and go out and spray indiscriminately all over the place.

So in answer to the Senator, I believe that many practical, alternative means are available right now. But again I say, the Secretary must consider the practicability and the economic feasibility for any standards. So that is the protection against arbitrariness on anything he may propose.

Mr. MUSKIE. That is the value of the Senator's amendment. It increases the pressure to recognize the availability of other means of controlling pests than with hard pesticides. If we do not concentrate on that and enlarge the possibilities in this respect, we will be wasting, perhaps, the last chance we will have to avoid the massive dispersal of hard pesticides into the environment.

I am delighted to cosponsor the amendment. I compliment the Senator on becoming, in my judgment, the most knowledgeable expert in the Senate on this problem.

Mr. NELSON. Mr. President, incidentally, I might say to the Senate, that my staff and the staff of the Senator from Maine will get together and develop a legislative proposal establishing standards for the components of pesticides, taking into consideration their persistence, degradability, and toxicity. This is the next step that must follow so that we can determine if pesticides, like detergents, should be subject to certain standards in order to protect the environment.

Mr. MUSKIE. I thank the Senator.

Mr. TYDINGS. Mr. President, as a cosponsor of amendment No. 132, I congratulate the junior Senator from Wisconsin (Mr. NELSON) for his tireless efforts to call attention to the environmental danger stemming from the widespread and often indiscriminate use of persistent pesticides.

Toxic residues of these chemical compounds are showing up in our air and water, and, through the multiplying effect of the food chain, in human beings as well.

The effect of these poisons on fish and wildlife are well known. Our animal resources can be killed outright, as the Coho salmon were, or face gradual destruction, if not extinction, as are the brown pelican and the bald eagle.

The effect of pesticide residues on man are not yet fully known. Presently there is no evidence that the increasing amounts of pesticides in fact harm human beings. Yet common sense tells us that absorbing poisonous chemicals is not healthy.

The long-term health impact on man of persistent pesticides may well be most damaging.

Mr. President, in late July I introduced wide ranging pesticide protection legislation. The bill, S. 2747, directs the Secretary of Health, Education, and Welfare to make a complete study of the use and effects of pesticides. It transfers the pesticide regulatory functions from the Department of Agriculture to the Department of Health, Education, and Welfare. It removes the exemption from registration and labeling of those pesticides intended solely for export.

Finally, the bill places a 4-year moratorium on four of the more persistent and powerful pesticides.

It is perhaps the most comprehensive legislation on pesticides yet introduced in the Senate. But it is unlikely to go anywhere and now will serve only as a point of discussion.

Yet what is required now is not just talk but action as well. Senator NELSON'S amendment is the first step toward protecting our environment from toxic pesticides. I fully support his amendment and again congratulate the Senator for alerting us to the threat.

Mr. HART. Mr. President, I am very pleased to cosponsor Senator NELSON'S amendment to S. 7 which would require the Secretary of the Interior to develop water quality criteria for pesticides. These criteria would then be used by the States as a basis for the adoption of standards to effectively control pesticide pollution of our lakes and rivers.

As with most of our clean water efforts, the need to develop standards which will help to reduce the quantity of persistent pesticides entering our water is long overdue. For many years scientists have been warning that the large-scale and indiscriminate introduction of these chemicals into our environment may be doing serious harm. But only today are people generally beginning to realize that although agricultural production has increased and disease control has been improved through the use of persistent pesticides, these short-term gains may have been purchased at the price of irreversible disruption of many ecological systems.

The so-called magnification effect of pesticides on fish and wildlife has now been well documented. Fish, feeding on miscroscopic organisms which contain persistent pesticides, assimilate these chemicals into their own systems. In addition, through normal gill action, a fish appears to effectively filter pesticides directly from the water. In both cases, the pesticide is stored up in the body fat of the fish where it becomes increasingly more concentrated. Then, moving upward in the food chain, each successive predator assimilates greater and greater concentrations of these pesticides from the smaller fish on which it feeds. Fish at the end of the food chain, such as the Lake Michigan coho salmon, now contain DDT concentrations ranging up to 19 parts per million, and fish-eating birds, such as the osprey and eagle, contain even higher levels of this pesticide.

The effects of such concentrations of persistent pesticides on fish and wildlife are daily becoming better understood. For example, Prof. Howard Johnson of Michigan State University has reported upon the reproductive problems DDT has created for the Lake Michigan coho salmon. Apparently the female salmon passes some of the DDT on to her eggs in concentrations ranging between five and seven parts per million. After the fry hatches from these eggs, they begin to absorb the yolk sac, but as they do, the DDT remaining in the yolk becomes more and more highly concentrated. At the last stages of absorption, DDT concentrations become six to 12 times higher than those in the actual body tissue of the fry and this high level of DDT has proven fatal to a high percentage of the fry.

Slightly different problems have occurred with fish-eating birds. Here the high concentrations of DDT apparently upset the bird's liver enzyme balance and as a result affect its calcium metabolism. The result has been that these birds have produced eggs which have exceptionally brittle shells. In most cases the mother is unable to hatch these eggs, because she accidently breaks the shell. In one case reported by the Audobon Society, an embryo was born without a shell altogether; it was encased only in a membrane.

Last week the Commerce Committee's Subcommittee on Energy, Natural Resources, and the Environment, which I chair, held field hearings in Michigan to consider the effects of pesticides on sports and commercial fisheries. At these hearings Prof. Joseph Hickey of the University of Wisconsin commented on the serious disruption which DDT has caused to fish-eating bird populations. Branding DDT as the "compound of extinction," Professor Hickey stated:

> In a series of closely integrated studies, British, Canadian, and American scientists have proven that similar reproductive failures (1) occured in 1947 in peregrine falcons; (2) involve fish-eating birds like bald eagles, ospreys, brown pelicans, double-breasted cormorants, and herring gulls; (3) are producing regional extinction in some species and continentally wide extinction in others; and (4) are due to DDT. There is simply no scientific doubt about these statements.

He then went on to state:

> We have lost at least 95 per cent of our nesting peregrine falcons—perhaps the supreme example of avian evolution—in the United States south of Canada, and we may very well lose its entire subspecies in North America. We are going to lose our national bird, the bald eagle, as a nesting species on the shores of the Great Lakes, not necessarily on inland lakes. We have lost the brown pelican on the west side of the Gulf of Mexico. And we will lose it on the coast of California. These are pollution effects due to DDT. The facts are solid and the result of careful, painstaking research.

[p. 28998]

Much more speculative at the present time are questions about whether consumption of DDT or other persistent pesticides by man could seriously harm his health or well-being. Nevertheless, the evidence of its harm to birds and fish is sufficient to cause grave concern. And recent research efforts are beginning to produce additional disturbing results. For example, earlier this year I released a report of a study which had been conducted for the National Cancer Institute. This study revealed that when a group of mice was fed a mixture containing 140 parts per million of DDT over a period of 81 weeks, 63 percent developed tumors. With a control group of mice, only 16 percent developed tumors, indicating that the mice exposed to DDT were approximately four times more likely to develop tumors than mice not so exposed. In describing the DDT-induced tumors, the report states:

> It seems more reasonable to conclude that the great majority had malignant potentiality.

In addition, at the Environmental Subcommittee hearings on pesticides which were held last May, we asked the Food and Drug Administration whether they could summarize some of their work on the mutagenic effects of pesticides. One of the investigations which they described involves a study of 40 volunteers who are heavy pesticide users and 20 control subjects who are examined monthly to determine what leukocyte chromosome damage can be associated with the exposure to pesticides. According to the FDA:

> Preliminary results indicate that during midsummer the exposed group had something on the order of five times as many chromosome abberations as the control group. So far this study has not been able to make comparisons between the groups at other times of the year.

The Food and Drug Administration, concerned with the results of the expanding volume of research on pesticides, has moved to set pesticide tolerances on many food products. In the case of fish, an interim tolerance level of five parts per mission has been established. Although there is little question that the FDA is taking proper precautions in setting these tolerances, there is also little doubt that this action will seriously disrupt, if not destroy, the fishing industry on Lake Michigan. The coho salmon can no longer be marketed in interstate commerce because of its high DDT concentrations, and other commercially important fish which are lower down in the lake's food chain, such as the chub, now appear to be building up DDT concentrations in excess of the minimum FDA tolerances. Analyses by the Michigan field office of the Bureau of Commercial Fisheries indicate that the DDT concentration in some chubs now exceeds nine parts per million. Lake Michigan lake trout, too, also frequently contain concentrations in excess of the FDA's minimum tolerances.

To preserve many of our country's unique forms of life from extinction, to reverse the grave ecological damage which we are presently causing, and to restore the vitality of our freshwater fisheries, it is imperative that we begin now to upgrade the quality of our water. Establishing water tolerance levels for pesticides—and then rigidly enforcing these standards—is an essential step toward this goal. We should emphasize, however, that because very minute quantities of persistent pesticides within water — measured in terms of parts per trillion—cause severe harm to aquatic organisms which concentrate these pesticides within their systems, water quality standards should be based on the pesticide levels found in fish taken from the water, and not on the water itself. Only in this manner can we readily determine when the amount of pesticides in our waters is reaching dangerous levels.

Mr. President, I reiterate my great pleasure in supporting this amendment, and I earnestly hope that not only is it adopted, but that meaningful standards are forthcoming in the very near future.

The PRESIDING OFFICER. The question is on agreeing to the amendment, No. 132, of the Senator from Wisconsin.

The amendment was agreed to.

Mr. MUSKIE, Mr. President, I move that the vote by which the amendment was agreed to be reconsidered.

Mr. BYRD of West Virginia. Mr. President, I move that the motion to reconsider be laid on the table.

The motion to lay on the table was agreed to.

Mr. NELSON. Mr. President, I ask unanimous consent to have printed in the RECORD a series of technical studies taken from various scientific and conservation magazines.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From Scientific American, March 1967]

TOXIC SUBSTANCES AND ECOLOGICAL CYCLES

(By George M. Woodwell)

The vastness of the earth has fostered a tradition of unconcern about the release of toxic wastes into the environment. Billowing clouds of smoke are diluted to apparent nothingness; discarded chemicals are flushed away in rivers; insecticides "disappear" after they have done their job; even the massive quantities of radioactive debris of nuclear explosives are diluted in the apparently infinite volume of the environment. Such pollutants are indeed diluted to traces—to levels infinitesimal by ordinary standards, measured as parts per billion or less in air, soil and water. Some pollutants do disappear; they are immobilized or decay to harmless substances. Others last, sometimes in toxic form, for long periods. We have learned in recent years that dilution of persistent pollutants even to trace levels detectable only by refined techniques is no guarantee of safety. Nature has ways of concentrating substances that are frequently surprising and occasionally disastrous.

We have had dramatic examples of one of the hazards in the dense smogs that blanket our cities with increasing frequency. What is less widely realized is that there are global, long-term ecological processes that concentrate toxic substances, sometimes hundreds of thousands of times above levels in the environment. These processes include not only patterns of air and water circulation but also a complex series of biological mechanisms. Over the past decade detailed studies of the distribution of both radioactive debris and pesticides have revealed patterns that have surprised even biologists long familiar with the unpredictability of nature.

Major contributions to knowledge of these patterns have come from studies of radioactive fallout. The incident that triggered worldwide interest in large-scale radioactive pollution was the hydrogen-bomb test at Bikini in 1954 known as "Project Bravo." This was the test that inadvertently dropped radioactive fallout on several Pacific islands and on the Japanese fishing vessel *Lucky Dragon*. Several thousand square miles of the

Pacific were contaminated with fallout radiation that would have been lethal to man. Japanese and U.S. oceanographic vessels surveying the region found that the radioactive debris had been spread by wind and water, and, more disturbing, it was being passed rapidly along food chains from small plants to small marine organisms that ate them to large animals (including the tuna, a staple of the Japanese diet).

The U.S. Atomic Energy Commission and agencies of other nations, particularly Britain and the U.S.S.R., mounted a large international research program, costing many millions of dollars, to learn the details of the movement of such debris over the earth and to explore its hazards. Although these studies have been focused primarily on radioactive materials, they have produced a great deal of basic information about pollutants in general. The radioactive substances serve as tracers to show the transport and concentration of materials by wind and water and the biological mechanisms that are characteristic of natural communities.

One series of investigations traced the worldwide movement of particles in the air. The tracer in this case was strontium 90, a fission product released into the earth's atmosphere in large quantities by nuclear-bomb tests. Two reports in 1962—one by S. Laurence Kulp and Arthur R. Schulert of Columbia University and the other by a United Nations committee—furnished a detailed picture of the travels of strontium 90. The isotope was concentrated on the ground between the latitudes of 30 and 60 degrees in both hemispheres, but concentrations were five to 10 times greater in the Northern Hemisphere, where most of the bomb tests were conducted.

It is apparently in the middle latitudes that exchanges occur between the air of upper elevations (the stratosphere) and that of lower elevations (the troposphere). The larger tests have injected debris into the stratosphere; there it remains for relatively long periods, being carried back into the troposphere and to the ground in the middle latitudes in late winter or spring. The mean "half-time" of the particles' residence in the stratosphere (that is, the time for half of a given injection to fall out) is from three months to five years, depending on many factors, including the height of the injection, the size of the particles, the latitude of injection and the time of year. Debris injected into the troposphere has a mean half-time of residence ranging from a few days to about a month. Once airborne, the particles may travel rapidly and far. The time for one circuit around the earth in the middle latitudes varies from 25 days to less than 15. (Following two recent bomb tests in China fallout was detected at the Brookhaven National Laboratory on Long Island respectively nine and 14 days after the tests.)

Numerous studies have shown further that precipitation (rain and snowfall) plays an important role in determining where fallout will be deposited. Lyle T. Alexander of the Soil Conservation Service and Edward P. Hardy, Jr., of the AEC found in an extensive study in Clallam County, Washington, that the amount of fallout was directly proportional to the total annual rainfall.

It is reasonable to assume that the findings about the movement and fallout of radioactive debris also apply to other particles of similar size in the air. This conclusion is supported by a recent report by Donald F. Gatz and A. Nelson Dingle of the University of Michigan, who showed that the concentration

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of pollen in precipitation follows the same pattern as that of radioactive fallout. This observation is particularly meaningful because pollen is not injected into the troposphere by a nuclear explosion; it is picked up in air currents from plants close to the ground. There is little question that dust and other particles, including small crystals of pesticides, also follow these patterns.

From these and other studies it is clear that various substances released into the air are carried widely around the world and may be deposited in concentrated form far from the original source. Similarly, most bodies of water — especially the oceans — have surface currents that may move materials five to 10 miles a day. Much higher rates, of course, are found in such major oceanic currents as the Gulf Stream. These currents are one more physical mechanism that can distribute pollutants widely over the earth.

The research programs of the AEC and other organizations have explored not only the pathways of air and water transport but also the pathways along which pollutants are distributed in plant and animal communities. In this connection we must examine what we mean by a "community."

Biologists define communities broadly to include all species, not just man. A natural community is an aggregation of a great many different kinds of organisms, all mutually interdependent. The basic conditions for the integration of a community are determined by physical characteristics of the environment such as climate and soil. Thus a sand dune supports one kind of community, a freshwater lake another, a high mountain still another. Within each type of environment there develops a complex of organisms that in the course of evolution becomes a balanced, self-sustaining biological system.

Such a system has a structure of interrelations that endows the entire community with a predictable development pattern, called "succession," that leads toward stability and enables the community to make the best use of its physical environment. This entails the development of cycles through which the community as a whole shares certain resources, such as mineral nutrients and energy. For example, there are a number of different inputs of nutrient elements into such a system. The principal input is from the decay of primary minerals in the soil. There are also certain losses, mainly through the leaching of substances into the underlying water table. Ecologists view the cycles in the system as mechanisms that have evolved to conserve the elements essential for the survival of the organisms making up the community.

One of the most important of these cycles is the movement of nutrients and energy from one organism to another along the pathways that are sometimes called food chains. Such chains start with plants, which use the sun's energy to synthesize organic matter; animals eat the plants; other animals eat these herbivores, and carnivores in turn may constitute additional levels feeding on the herbivores and on one another. If the lower orders in the chain are to survive and endure, there must be a feedback of nutrients. This is provided by decay organisms (mainly microorganisms) that break down organic debris into the substances used by plants. It is also obvious that the community will not survive if essential links in the chain are eliminated; therefore the preying of one level on another must be limited.

Ecologists estimate that such a food chain allows the transmission of roughly 10 percent of the energy entering one level to the next level above it, that is, each level can pass on 10 percent of the energy it receives from below without suffering a loss of population that would imperil its survival. The simplest version of a system of this kind takes the form of a pyramid, each successively higher population receiving about a tenth of the energy received at the level below it.

Actually nature seldom builds communities with so simple a structure. Almost invariably the energy is not passed along in a neatly ordered chain but is spread about to a great variety of organisms through a sprawling, complex web of pathways. The more mature the community, the more diverse its makeup and the more complicated its web. In a natural ecosystem the network may consist of thousands of pathways.

This complexity is one of the principal factors we must consider in investigating how toxic substances may be distributed and concentrated in living communities. Other important basic factors lie in the nature of the metabolic process. For example, of the energy a population of organisms receives as food, usually less than 50 percent goes into the construction of new tissue, the rest being spent for respiration. This circumstance acts as a concentrating mechanism: a substance not involved in respiration and not excreted efficiently may be concentrated in the tissues twofold or more when passed from one population to another.

Let us consider three types of pathways for toxic substances that involve man as the ultimate consumer. The three examples, based on studies of radioactive substances, illustrate the complexity and variety of pollution problems.

The first and simplest case is that of strontium 90. Similar to calcium in chemical behavior, this element is concentrated in bone. It is a long-lived radioactive isotope and is a hazard because its energetic beta radiation can damage the mechanisms involved in the manufacture of blood cells in the bone marrow. In the long run the irradiation may produce certain types of cancer. The route of strontium 90 from air to man is rather direct: we ingest it in leafy vegetables, which absorbed it from the soil or received it as fallout from the air, or in milk and other dairy products from cows that have fed on contaminated vegetation. Fortunately strontium is not usually concentrated in man's food by an extensive food chain. Since it lodges chiefly in bone, it is not concentrated in passing from animal to animal in the same ways other radioactive substances may be (unless the predator eats bones!).

Quite different is the case of the radioactive isotope cesium 137. This isotope, also a fission product, has a longlived radioactivity (its half-life is about 30 years) and emits penetrating gamma rays. Because it behaves chemically like potassium, an essential constituent of all cells, it becomes widely distributed once it enters the body. Consequently it is passed along to meat-eating animals, and under certain circumstances it can accumulate in a chain of carnivores.

A study in Alaska by Wayne C. Hanson, H. E. Palmer and B. I. Griffin of the AEC's Pacific-Northwest Laboratory showed that the concentration factor for cesium 137 may be two or three for one step in a food chain. The first link of the chain in this case was lichens growing in the Alaskan forest and tundra. The lichens collected cesium 137 from fallout in rain. Certain caribou in Alaska live mainly on lichens during the winter, and caribou meat in turn is the principal diet of Eskimos in the same areas. The investigators found that caribou had accumulated about 15 micromicrocuries of cesium radioactivity per gram of tissue in their bodies. The Eskimos who fed on these caribou had a concentration twice as high (about 30 micromicrocuries per gram of tissue) after eating many pounds of caribou meat in the course of a season. Wolves and foxes that ate caribou sometimes contained three times the concentration in the flesh of the caribou. It is easy to see that in a longer chain, involving not just two animals but several, the concentration of a substance that was not excreted or metabolized could be increased to high levels.

A third case is that of iodine 131, another gamma ray emitter. Again the chain to man is short and simple: The contaminant (from fallout) comes to man mainly through cows' milk, and thus the chain involves only grass, cattle, milk and man. The danger of iodine 131 lies in the fact that iodine is concentrated in the thyroid gland. Although iodine 131 is short-lived (its half-life is only about eight days), its quick and localized concentration in the thyroid can cause damage. For instance, a research team from the Brookhaven National Laboratory headed by Robert Conard has discovered that children on Rongelap Atoll who were exposed to fallout from the 1954 bomb test later developed thyroid nodules.

The investigations of the iodine 131 hazard yielded two lessons that have an important bearing on the problem of pesticides and other toxic substances released in the environment. In the first place we have had a demonstration that the hazard of the toxic substance itself often tends to be underestimated. This was shown to be true of the exposure of the thyroid to radiation. Thyroid tumors were found in children who had been treated years before for enlarged thymus glands with doses of X-rays that had been considered safe. As a result of this discovery and studies of the effects of iodine 131, the Federal Radiation Council in 1961 issued a new guide reducing the permissible limit of exposure to ionizing radiation to less than a tenth of what had previously been accepted. Not the least significant aspect of this lesson is the fact that the toxic effects of such a hazard may not appear until long after the exposure; on Rongelap Atoll 10 years passed before the thyroid abnormalities showed up in the children who had been exposed.

The second lesson is that, even when the pathways are well understood, it is almost impossible to predict just where toxic substances released into the environment will reach dangerous levels. Even in the case of the simple pathway followed by iodine 131 the eventual destination of the substance and its effects on people are complicated by a great many variables: the area of the cow's pasture (the smaller the area, the less fallout the cow will pick up); the amount and timing of rains on the pasture (which on the one hand may bring down fallout but on the other may wash it off the forage); the extent to which the cow is given stored, uncontaminated feed; the amount of iodine the cow secretes in its milk; the amount of milk in the diet of the individual consumer, and so on.

If it is difficult to estimate the nature and extent of the hazards from radioactive fallout, which have been investigated in great detail for more than a decade by an international research program, it must be said that we are in a poor position indeed to estimate the hazards from pesticides. So far the amount of research effort given to the ecological effects of these poisons has been comparatively small, although it is increasing rapidly. Much has been learned, however, about the movement and distribution of pesticides in the environment, thanks in part to the clues supplied by the studies of radioactive fallout.

Our chief tool in the pesticide inquiry is DDT. There are many reasons for focusing on DDT; it is long-lasting, it is now comparatively easy to detect, it is by far the most widely used pesticide and it is toxic to a broad spectrum of animals, including man. Introduced only a quarter-century ago [p. 29000] and spectacularly successful during World War II in controlling body lice and therefore typhus, DDT quickly became a universal weapon in agriculture and in public health campaigns against disease-carriers. Not surprisingly, by this time DDT has thoroughly permeated our environment. It is found in the air of cities, in wildlife all over North America and in remote corners of the earth, even in Adélie penguins and skua gulls (both carnivores) in the Antarctic. It is also found the world over in the fatty tissue of man. It is fair to say that there are probably few populations in the world that are not contaminated to some extent with DDT.

We now have a considerable amount of evidence that DDT is spread over the earth by wind and water in much the same patterns as radioactive fallout. This seems to be true in spite of the fact that DDT is not injected high into the atmosphere by an explosion. When DDT is sprayed in the air, some fraction of it is picked up by air currents as pollen is, circulated through the lower troposphere and deposited on the ground by rainfall. I found in tests in Maine and New Brunswick, where DDT has been sprayed from airplanes to control the spruce budworm in forests, that even in the open, away from trees, about 50 percent of the DDT does not fall to the ground. Instead it is probably dispersed as small crystals in the air. This is true even on days when the air is still and when the low-flying planes release the spray only 50 to 100 feet above treetop level. Other mechanisms besides air movement can carry DDT for great distances around the world. Migrating fish and birds can transport it thousands of miles. So also do oceanic currents. DDT has only a low solubility in water (the upper limit is about one part per billion), but as algae and other organisms in the water absorb the substance in fats, where it is highly soluble, they make room for more DDT to be dissolved into the water. Accordingly water that never contains more than a trace of DDT can continuously transfer it from deposits on the bottom to organisms.

DDT is an extremely stable compound that breaks down very slowly in the environment. Hence with repeated spraying the residues in the soil or water basins accumulate. Working with Frederic T. Martin of the University of Maine, I found that in a New Brunswick forest where spraying had been discontinued in 1958 the DDT content of the soil increased from half a pound per acre to 1.3 pounds per acre in the three years between 1958 and 1961. Apparently the DDT residues were carried to the ground very slowly on foliage and decayed very little. The conclusion is that DDT has a long half-life in the trees and soil of a forest, certainly in the range of tens of years.

Doubtless there are many places in the world where reservoirs of DDT are accumulating. With my colleagues Charles F. Wurster, Jr., and Peter A. Isaacson of the State University of New York at Stony Brook, I recently sampled a marsh along the south shore of Long Island that had been sprayed with DDT for 20 years to control mosquitoes. We found that the DDT residues in the upper layer of mud in this marsh ranged up to 32 pounds per acre!

We learned further that plant and animal life in the area constituted a chain that concentrated the DDT in spectacular fashion. At the lowest level the plankton in the water contained .04 part per million of DDT; minnows contained one part per million, and a carnivorous scavenging bird (a ring-billed gull) contained about 75 parts per million in its tissues (on a whole-body, wetweight basis). Some of the carnivorous animals in this community had concentrated DDT by a factor of more than 1,000 over the organisms at the base of the ladder.

A further tenfold increase in the concentrations along this food web would in all likelihood result in the death of many of the organisms in it. It would then be impossible to discover why they had disappeared. The damage from DDT concentration is particularly serious in the higher carnivores. The mere fact that conspicuous mortality is not observed is no assurance of safety. Comparatively low concentrations may inhibit reproduction and thus cause the species to fade away.

That DDT is a serious ecological hazard was recognized from the beginning of its use. In 1946 Clarence Cottam and Elmer Higgins of the U.S. Fish and Wildlife Service warned in the *Journal of Economic Entomology* that the pesticide was a potential menace to mammals, birds, fishes and other wildlife and that special care should be taken to avoid its application to streams, lakes and coastal bays because of the sensitivity of fishes and crabs. Because of the wide distribution of DDT the effects of the substance on a species of animal can be more damaging than hunting or the elimination of a habitat (through an operation such as dredging marshes). DDT affects the entire species rather than a single population and may well wipe out the species by eliminating reproduction.

Within the past five years, with the development of improved techniques for detecting the presence of pesticide residues in animals and the environment, ecologists have been able to measure the extent of the hazards presented by DDT and other persistent general poisons. The picture that is emerging is not a comforting one. Pesticide residues have now accumulated to levels that are catastrophic for certain animal populations, particularly carnivorous birds. Furthermore, it has been clear for many years that because of their shotgun effect these weapons not only attack the pests but also destroy predators and competitors that normally tend to limit proliferation of the pests. Under exposure to pesticides the pests tend to develop new strains that are resistant to the chemicals. The result is an escalating chemical warfare that is self-defeating and has secondary effects whose costs are only beginning to be measured. One of the costs is wildlife, notably carnivorous and scavenging birds such as hawks and eagles. There are others: destruction of food webs aggravates pollution problems, particularly in bodies of water that receive mineral nutrients in sewage or in water draining from heavily fertilized agricultural lands. The plant populations, no longer consumed by animals, fall to the bottom to decay anaerobically, producing hydrogen sulfide and other noxious gases, further degrading the environment.

Location	Organism	Tissue	Concentration (parts per million)
United States (Average).	Man	Fat	11.0.
Alaska (Eskimo)			2.8.
England			2.2.
West Germany			2.3.
France			5.2.
Canada			5.3.
Hungary			12.4.
Israel			19.2.
India			12.8-31.0.
United States:			
California	Plankton		5.3.
Do	Bass	Edible Flesh	4–138.
Do	Grebes	Visceral Fat	Up to 1,600.
Montana	Robin	Whole Body	6.8–13.9.
Wisconsin	Crustacea		0.41.
Do	Chub	Whole Body	4.52.
Do	Gull	Brain	20.8.
Missouri	Bald Eagle	Eggs	1.1–5.6.
Connecticut	Osprey	do	6.5.
Florida	Dolphin	Blubber	About 220.
Canada	Woodcock	Whole Body	1.7.
Antarctica	Penguin	Fat	0.015–0.18.
Antarctica	Seal	Fat	0.042–0.12.
Scotland	Eagle	Eggs	1.18.
New Zealand	Trout	Whole Body	0.6–0.8.

Note: DDT residues, which include the derivatives DDD and DDE as well as DDT itself, have apparently entered most food webs. These data were selected from hundreds of reports that show DDT has a worldwide distribution, with the highest concentrations in carnivorous birds.

The accumulation of persistent toxic substances in the ecological cycles of the earth is a problem to which mankind will have to pay increasing attention. It affects many elements of society, not only in the necessity for concern about the disposal of wastes but also in the need for a revolution in pest control. We must learn to use pesticides that have a short half-life in the environment—better yet, to use pest-control techniques that do not require applications of general poisons. What has been learned about the dangers in polluting ecological cycles is ample proof that there is no longer safety in the vastness of the earth.

DDT Residues and Declining Reproduction in Bermuda Petrel

(Abstract. Residues of DDT [1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane] averaging 6.44 parts per million in eggs and chicks of the carnivorous Bermuda petrel indicate widespread contamination of an oceanic food chain that is remote from applications of DDT. Reproduction by the petrel has declined during the last 10 years at the annual rate of 3.25 percent; if the decline continues, reproduction will fail completely by 1978. Concentrations of residues are similar to those in certain terrestrial carnivorous birds whose productivity is also declining. Various considerations implicate contamination by insecticides as a probable major cause of the decline.)

Many oceanic birds nested on Bermuda in 1609 when the first settlers arrived, the most abundant apparently being the Bermuda petrel, *Pterodroma cahow*. Within 20 years man and his imported mammals virtually exterminated those species; for nearly 300 years it was considered extinct. Several records of specimens since 1900 were followed in 1951 by discovery of a small breeding colony (1), and in 1967 22 pairs nested on a few rocky islets off Bermuda. With a total population of about 100 the petrel is among the world's rarest birds.

A wholly pelagic species, *P. cahow* visits land only to breed, breeds only on Bermuda, and arrives and departs only at night. The single egg is laid underground at the end of a long burrow. When not in the burrow the bird feeds far at sea, mainly on cephalopods; when not breeding it probably ranges over much of the North Atlantic (1).

Reproduction by *P. cahow* has declined recently. The data since 1958 (Table 1) show an annual rate of decline of 3.25±1.05 percent; the negative slope of a weighted regression is significant (P, .015; F test). If this linear decline continues, reproduction will fail completely by 1978, with extinction of the species. Many recent reports have correlated diminished reproduction by certain carnivorous birds with contamination by chlorinated hydrocarbon insecticides (2–7). As the terminal member of a pelagic food chain, presumably feeding over much of the North Atlantic, the petrel may be expected to concentrate by many orders of magnitude any stable, lipid soluble chemicals, such as chlorinated hydrocarbon insecticides, present in lower trophic levels (2, 3, 8). In fact it should serve as an ideal environmental monitor for detection of insecticide contamination as a general oceanic pollutant, rather than contamination resulting directly from treatment of a specific land area (9). When we analyzed several specimens of *P. cahow* for chlorinated hydrocarbon insecticides, all samples contained DDT residues (10).

During March 1967 five unhatched eggs and dead chicks were collected from unsuccessful petrel burrows and stored frozen. The small size of the population precluded the sampling of living birds. Samples were analyzed for DDT, *o,p*-DDT, DDE, DDD, dieldrin, and endrin by electron-capture gas chromatography; the results are summarized in Table 2. No *o,p*-DDT, diedrin, or

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endrin was detected, but an independent laboratory detected a trace of dieldrin.

Certain identifications were confirmed by thin-layer chromatography (11) as follows: After Florisil cleanup (12), the unknown sample was spotted on a thin-layer plate with 1-µg authentic standard samples on both sides. After development, the unknown was masked by a strip of paper, and the standards were sprayed with chromogenic reagent (11). When spots were visible following exposure to ultraviolet light, the masking was removed, horizontal lines were drawn between the standard spots in order to locate corresponding compounds in the unknown, and these areas were scraped from the plate and extracted with a few drops of a mixture of hexane and acetone (9:1 by volume). Injection into the gas chromatograph confirmed the presence of DDT, DDE, and DDD by showing the appropriate single peaks for these compounds. This confirmation procedure was employed because the electron-capture detector is more sensitive than the chromogenic spray reagent in detecting minute amounts of these materials.

Coincidental with diminishing reproduction by the Bermuda petrel is the presence of DDT residues averaging 6.44 parts per million (ppm) in its eggs and chicks. In itself this coincidence does not establish a causal relation, but these findings must be evaluated in the light of other studies. Whereas a healthy osprey *(Pandion haliaetus)* population produces 2.2 to 2.5 young per nest, a Maryland colony containing DDT residues of 3.0 ppm in its eggs yielded 1.1 young per nest, and a Connecticut colony containing 5.1 ppm produced only 0.5 young per nest; the Connecticut population has declined 30 percent annually for the last 9 years (4). In New Brunswick, breeding success of American woodcocks *(Philohela minor)* showed a statistically significant inverse correlation with the quantity of DDT applied to its habitat in a given year. Furthermore, during 1962 and 1963, birds from unsprayed Nova Scotia showed breeding success nearly twice as great as did those from sprayed New Brunswick, where woodcock eggs averaged 1.3 ppm of DDT residues during those years (5).

TABLE 1.—REPRODUCTIVE SUCCESS OF THE BERMUDA PETREL BETWEEN 1958 AND 1967[1]

Year	Pairs	Chicks	Success (percent)
1958	6 (1)	4	66.7
1959	5 (2)	2	40.0
1960	13 (3)	6	46.2
1961	18 (1)	12	66.7
1962	19	9	47.4
1963	17 (1)	9	52.9
1964	17 (1)	8	47.1
1965	20	8	40.0
1966	21	6	28.6
1967	22	8	36.4

[1] Percentages of established adult pairs under observation whose chicks survived 2 weeks after hatching. Numbers of pairs of unknown success (not included in calculations) appear in parentheses. Data from 1961 to 1967 are believed to represent the total breeding population; earlier, not all burrows had been discovered. The decline in reproductive success follows the linear relation $y = a + bx$ (y, reproductive success; a, a constant; b, annual percentage decline in success; x, year). The regression weighted by numbers of pairs: $y = 251.9 - 3.25x$.

In Britain five species of raptors, including the peregrine falcon *(Falco peregrinus)* and golden eagle *(Aquila chrysaetos)*, carried residues of chlorinated hydrocarbon insecticides in their eggs, averaging 5.2 ppm; each of these species has shown a decline in reproduction and total population during recent years. By comparison, residues in the eggs of five species of corvids averaged 0.9 ppm, and breeding success and numbers have been maintained *(6)*. It is noteworthy that during the last decade the peregrine has become extinct as a breeding bird in the eastern United States *(13)*. Residues in bald eagle *(Haliaetus leucocephalus)* eggs averaged 10.6 ppm, and this species also shows declining reproduction and population *(7)*. Lake Michigan herring gulls *(Larus agentatus)*, exhibiting very low reproductive success, averaged 120 to 227 ppm of DDT residues in the eggs *(3)*, the suggestion being that susceptibility varies widely between species.

In most of the above instances, including *P. cahow*, reduced success in breeding resulted primarily from mortality of chicks before and shortly after hatching. Bobwhites (*Colinus virginianus*) and pheasants (*Phasianus colchicus*), fed sublethal diets of DDT or dieldrin, gave similar results *(14)*; a mechanism explaining chick mortality from dieldrin poisoning during the several days after hatching has been presented *(15)*.

From studies of these birds and other avian carnivores a very widespread, perhaps worldwide, decline among many species of carnivorous birds is apparent. The pattern of decline is characterized by reduced success in reproduction correlated with the presence of residues of chlorinated hydrocarbon insecticides—primarily DDT. Our data for the Bermuda petrel are entirely consistent with this pattern.

Observations of aggressive behavior, increased nervousness, chipped eggshells, increased egg-breakage, and egg-eating by parent birds of several of the above species *(3, 6, 13)* suggest symptoms of a hormonal disturbance or a calcium deficiency, or both. Moreover, DDT has been shown to delay ovulation and inhibit gonadal development in birds, probably by means of a hormonal mechanism, and low dosages of DDT or dieldrin in the diet of pigeons increased metabolism and steroid sex hormones by hepatic enzymes *(16)*. A direct relation between DDT and calcium functions has also been demonstrated, and these endocrine and calcium mechanisms could well be interrelated; DDT interferes with normal calcification of the arthropod nerve axon, causing hyperactivity of the nerve and producing symptoms similar to those resulting from calcium deficiency *(17)*. Dogs treated with calcium gluconate are very resistant to DDT poisoning *(18)*; female birds are more resistant than males *(19)*, perhaps because of calcium-mobilizing action of estrogenic hormones.

TABLE 2.—RESIDUES OF DDT (10) IN PARTS PER MILLION (WET WEIGHT) IN EGGS AND CHICKS OF THE BERMUDA PETREL, COLLECTED IN BERMUDA IN MARCH 1967; PROPORTIONS OF DDT, DDE, AND DDD ARE EXPRESSED AS PERCENTAGES OF THE TOTAL

Sample	Residues (parts per million)	Percentages		
		DDT	DDE	DDD
A, egg[1]	11.02	[2] 37	[2] 58	[2] 5
A, egg[1 3 4]	10.71	[2] 34	[2] 62	[2] 4
B, addled egg[1]	3.61	15	65	20
C, chick in egg[5]	4.52	33	64	3
D, chick in egg[5]	6.08	33	62	5
D, chick brain[4 5]	.57	30	54	16
E, chick, 1 to 2 days old	6.97	[2] 29	[2] 66	[2] 5
Average	6.44	31	62	7

[1] Egg showed no sign of development.

[2] Identity confirmed by thin-layer chromatography (11).

[3] Analysis 5 months later by Wisconsin Alumni Research Foundation, which also detected dieldrin at 0.02 p.p.m.

[4] Not included in averages.

[5] Fully developed chick died while hatching.

Of major importance, then, was the discovery that a significant ($P < .001$) and widespread decrease in calcium content of eggshells occurred between 1946 and 1950 in the peregrine falcon, golden eagle, and sparrowhawk, *Accipiter nisus (20)*. This decrease correlates with the widespread introduction of DDT into the environment during those years, and further correlates with the onset of reduced reproduction and of the described symptoms of calcium deficiency. These multiple correlations indicate a high probability that the decline in reproduction in most or all of these birds, including *P. cahow*, is causally related to their contamination by DDT residues.

Other potential causes of the observed decline for the Bermuda petrel appear unlikely. The bird has been strictly protected and isolated since 1957, and it seems that human disturbance can be discounted. In such a small population, inbreeding could become important, but hatching failure is now consistent in pairs having earlier records of successful breeding, and deformed chicks are never observed. Furthermore, the effects of inbreeding would not be expected to increase at a time when the total population, and probably the gene pool, is still increasing. The population increase results from artificial protection since 1957 from other limiting factors, especially competition for nest sites with tropic birds *(21)*.

It is very unlikely that the observed DDT residues in *P. cahow* were accumulated from Bermuda; the breeding grounds are confined to a few tiny, isolated, and uninhabited islets never treated with DDT, and the bird's feeding habits are wholly pelagic. Thus the presence of DDT residues in all samples can lead only to the conclusion that this oceanic food chain, presumably including the plankton, is contaminated. This conclusion is supported by reported analyses showing residues in related seabirds including two species of shearwaters from the Pacific *(22)*; seabird eggs *(9, 22)*; freshwater, estuarine, and coastal plankton *(2, 8, 23)*; plankton-feeding organisms *(2, 8, 9, 22, 23)*; and other marine animals from various parts of the world *(8, 22)*. These toxic chemicals are apparently very widespread within oceanic organisms *(8, 22)*, and the evidence suggests that their ecological effects are important.

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THE PEREGRINE SITUATION IN GREAT BRITAIN 1965–66

(By D. A. Ratcliffe)

(Monks Wood Experimental Station—The Nature Conservancy)

INTRODUCTION

In order to follow latest trends in the breeding population of the British Peregrine (*Falco peregrinus*), a sample census was continued in 1965 and 1966 on a scale similar to that of 1963–64. This paper summarises the results, and gives data on chemical analysis of the small samples of eggs taken during these two years.

CENSUS DATA

Observations on 200 territories in 1965 and 213 territories in 1966 (representing 240 different territories of the two-year period) are given in Table I, according to the six different regions of Great Britain recognised previously (Ratcliffe 1963). This sample is approximately one-third of the mean annual total of 650 territories estimated to be occupied regularly in Great Britain during the standard period 1930–39, or just under one-third of the total of 718 territories occupied at least once since 1930. Census data for 1961–64 are given for comparison. However, because of a bias against visiting previously deserted territories and reporting negative observations during the period 1963–66, the figures for these years are not directly comparable with those for 1961–62, and a correction has to be made (see Table I).

It is evident that there has been no appreciable change in level of breeding population since 1964, for although only 14 success-

TABLE I.—OCCUPATION OF PEREGRINE TERRITORIES, 1963–66

Year and region	Number of territories examined	Birds apparently absent	1 or both of the pair present but not proved to nest	Nesting, outcome unknown	Nested, but unsuccessfully (eggs or young lost)	Successful nesting (young reared)
1961: Total for Great Britain	431	173	118	17	41	91 (9)
1962: Total for Great Britain	488	247	119	22	35	77 (9)
1963: Total for Great Britain	200	110	34	4	13	39 (0)
1964: Total for Great Britain	203	109	28	3	15	48 (0)
1965:						
Southern England	42	40		1		1
Wales	34	26	6			2
Northern England	30	17	2		4	7
Southern Scotland	31	12	3	3	5	8
South and East Highlands	47	4	8	7	4	24
North and West Highlands	36	18	6	6	3	3
Total for Great Britain	220	117	25	17	16	45 (1)
1966:						
Southern England	42	40				2
Wales	40	34	3	1		2
Northern England	24	13	4	1	3	3
Southern Scotland	32	11	6	2	4	9
South and East Highlands	44	7	11	1	2	23
North and West Highlands	31	12	5	7	5	2
Total for Great Britain	213	117	29	12	14	41 (3)

Notes: To make approximate correction for comparison with 1961–62, the figures for 1963–66 regarding "birds apparently absent" should be increased by ¼, and those for "successful nesting" should be reduced by ⅓. These factors are derived as follows: The sample of eyries visited in each of the years 1963–66 is similarly biased (toward territories likely to give positive rather than negative records) by comparison with the much larger sample for 1961–62, and many eyries visited with negative results have evidently not been reported to me. If the 1962 data are subsampled to give a list of those eyries which were actually visited during 1963–66, simple calculation gives values of 44 percent for territory desertion and 24 percent for successful breeding pairs. The figures calculated from the full 1962 data are, however, 50 and 16 percent respectively, i.e. approximately ¼ more for territory desertion and ⅓ less for successful pairs. As the samples for 1961 and 1962 were closely comparable, the above correction factors apply also to 1961.

Actual breeding success for 1961 and 1962 is 19 and 13 percent, respectively, when broods taken by falconers are regarded as failures (as in Ratcliffe 1963), but to show more accurately the proportion of healthy broods potentially able to fledge, those taken by falconers have been included and give breeding success as a theoretical 21 and 16 percent. Broods taken by falconers (illegally after 1961) are bracketed alongside the totals.

ful eyries were known in 1966, against 45 in 1965, this is not a significant difference. The data certainly give no hint of overall improvement in the Peregrine situation during the last two years. Few records for the mainland of the North and West Highlands are available for 1965–66, and most of the data referring to this region are for Orkney and Shetland. It is clear that parts of the South and East Highlands are still the stronghold of the Peregrine in Britain, and breeding success has remained good in this region; but even here, a quarter of the inspected territories held apparently nonbreeding birds in 1966. In England and Wales together, successful breeding was limited to ten pairs in 1965 and seven pairs in 1966, and at least four-fifths of the territories visited were unoccupied in both years.

When the figures for 1965–66 are compared with those for 1963–64, the proportion of deserted territories is seen to have been fairly constant throughout, i.e. about 60 percent of the number of known territories visited, when correction for observation/recording bias has been made. Regarding breeding success, it should be noted that in 1965 and 1966 there were, respectively, 17 and 12 eyries where eggs were probably or certainly laid, but which were not re-visited to determine the final outcome; whereas in 1963 and 1964 there were only 4 and 3 such eyries. As the other data suggest that at least half the 'outcome unknown' eyries would be successful, the figures for successful nesting in the 1965–66 census samples would almost certainly be higher than those given in Table I. Even so, it is doubtful if there is valid evidence for a significant change in breeding success during the whole four-year period 1963–66; this has fluctuated from about 13 to 16 per cent of the number of known territories visited. There may have been a slight recovery in 1964 after the low ebb of 1963, but the figures may indicate merely the normal fluctuation of a population which has become relatively stabilised at a much reduced level; while, in any case, there is likely to be a degree of sampling and observational error.

By comparison with the fuller data for 1961–62, it would seem that the rapid decline of those years continued into 1963, but that the population then leveled off, and, at most, has since shown marginal improvement in breeding success alone. On the other hand, when data for each region are examined separately, the population of Southern Scotland has shown evident improvement in breeding success since 1963; in 1963, only 3 out of 19 inland territories visited had successful pairs, whereas in 1966, 8 out of 24 reared young. M. Gilbertson (pers. comm.) also reports an apparent improvement in Northern Ireland, where a total of only 5 young was reared in 14 territories examined in 1964, compared with a total of 11 young in 16 territories in 1966. These are the regions closest to the Scottish Highlands, and therefore the ones in which any recovery of the Peregrine population might be expected to show first.

PESTICIDE RESIDUES

Although only 12 Peregrine eggs have been analysed (by gas-liquid chromatography) for organo-chlorine pesticide residues in 1965–66, the results (Table II) are revealing. Despite the higher levels, compared with 1963–64, the sample is too small for the data to be regarded as valid evidence of an increase in contamination. However, the figures suggest that the voluntary restrictions on use of aldrin, dieldrin and heptachlor, in 1964, have (up to the spring of 1966) had no effect in reducing the contamination of the British Peregrine by residues of these pesticides. The figures for heptachlor in particular indicate that, despite statements to the contrary,

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there was still a considerable local use of this chemical during 1965–66.

Whilst only 5 egg analyses are available yet for the central part of the South and East Highlands, they show an appreciably lower mean level of contamination than the 22 eggs from Northern England and Southern Scotland, though the difference lies largely in the DDE component of the residues. This matches the differences between the first region and the second two in regard to both state of the population and breeding success; and it supports the earlier contention (Ratcliffe 1963, 1965) that contamination risk to the Peregrine is lower in the South and East Highlands than in most other parts of the British Isles. Even within the 5 Highland eggs there are suggestive differences; the two from Angus (within Peregrine reach of rich arable farm land) contain appreciably higher residues of DDE, dieldrin and heptachlor expoxide than those from the three Inverness-shire eyries, which were all remote from agricultural land.

The egg analyses for 1963–64 showed no difference between those from eyries which failed and those which produced flying young from the remaining eggs (Ratcliffe 1965). Now that more data are available, a slight difference shows when all egg analyses are thus separated; the figures are (total organochlorine residues) 17.4 p.p.m. for eggs from failed eyries and 12.7 p.p.m. for eggs from successful eyries. The difference is not statistically significant but it is suggestive.

In 1966, two eggs were examined for residues of mercury; one was blank (Table IIB, 1966/1) but the other (Table IIB, 1966/3) contained 0.3 p.p.m.

TABLE II.—ORGANO-CHLORINE RESIDUES IN PEREGRINE EGGS

A. CENTRAL SCOTTISH HIGHLANDS

Year	No.	County	pp DDE	pp TDE	pp DDT	Dieldrin	Heptachlor epoxide	BHC isomers	Total o/c residues
1963	[1] 1	Inverness	6.9			0.5	0.2	([2])	7.6
	[1] 2	Angus	5.4	0.6	0.8	.6	1.9	0.2	9.5
1966	[1] 1	Inverness	3.6		([2])	.1	([2])		3.7
	[1] 1	do	2.8		.1	.3	([2])		3.2
	[1] 3	Angus	7.8	.1	([2])	1.6	1.2		10.7
Mean			5.3	.1	.2	.6	.7	[3] .1	6.9

B. NORTHERN ENGLAND AND SOUTHERN SCOTLAND

Year	No.	County	pp DDE	pp TDE	pp DDT	Dieldrin	Heptachlor epoxide	BHC isomers	Total o/c residues
1963	[4] 1	Westmorland	15.8		0.4	0.7	2.9	0.2	20.0
	[4] 2	Cumberland	10.0			.4	.7	.1	11.2
	[1] 3	do.[3]	30.8			1.1	4.1	.1	36.1
	[4] 4	Dumfries[3]	2.6		.1	.1	.1	([2])	2.9
	[1] 5	Peebles	4.4		.1	.4	.6	([2])	5.5
	[4] 6	do.[3]	21.2		.1	.5	.6	.2	22.6
	[4] 7	do.[3]	23.2			.3	.3	.1	24.1
	[4] 8	Kirkcudbright	14.1			.7	.4	.1	15.3
	[4] 9	do	9.0		.1	.1	.4	.2	9.8
Mean for 1963			14.6		.1	.5	1.1	.1	16.4
1964	[4] 1	Dumfries[3]	4.7	([2])	([2])	1.3	.2	.6	6.8
	[4] 2	do	7.3			1.8	.7	.8	10.6
	[4] 3	Kirkcudbright[3]	10.8	0.5	.5	.1	.1	.5	12.5
	[4] 4	Peebles	12.0			.8	.4	.1	13.3
Mean for 1964			8.7	.1	.1	1.0	.4	.5	10.8
1965	[4] 1	Kirkcudbright[3]	22.3	.2	.3	.5	4.3	.4	28.0
	[1] 2	Dumfries[3]	10.2	.2	.2	.5	.2	.2	11.5
	[4] 3	Peebles	18.1	.1	.7	.5	.2	.2	19.8
	[1] 4	Cumberland[3]	25.0			.6	.8	.1	26.5
	[4] 5	Westmorland	24.0			.8	1.0		25.8
Mean for 1965			19.9	.1	.2	.6	1.3	.2	22.3
1966	[4] 1	Kirkcudbright[3]	22.0	.2	.2	.3	1.0		23.7
	[4] 2	do	22.0			.6	1.0		23.6
	[4] 3	do	13.0		.1	.2	.1		13.4
	[4] 4	Westmorland	23.0	([2])		.6	.5	2.8	28.9
Mean for 1966			20.0	.1	.1	.9	.7	.7	22.5
Overall mean			15.7	.1	.1	.7	.9	.3	17.8

[1] Successful eyrie; at least 1 young reared from remaining eggs.

[2] Trace.

[3] Less than figure shown.

[3] Unsuccessful eyrie; remaining eggs broken or failed to hatch.

[4] Same female for the same locality.

BREEDING SUCCESS, BROOD SIZE AND REPLACEMENT OF LOSSES

Of the 30 eyries which failed in 1965–66, egg breakage or disappearance of eggs (usually one by one and apparently due to parental destruction) was the cause of failure in 26. Mean brood size in successful eyries has continued to be low in regions south of the Highlands (average of 1.8 young for 24 known broods) and normal in the South and East Highlands (average of 2.5 young for 28 known broods).

I have recently been provided with data collected by the late W. C. Lawrie at a regular Lakeland eyrie between 1910 and 1939. The history is incomplete, but the following records are available of all successful nestings in which the brood-size was definitely known:

1913, 3 young
1914, 3 young
1920, 3 young
1922, 3 young
1924, 4 young
1925, 2 young
1926, 4 young
1927, 4 young
1928, 1 young
1930, 4 young
1931, 3 young
1936, 4 young
1939, 4 young

The mean of these 13 broods was 3.2 young, an appreciably higher figure than the national pre-war average of 2.5 young. Unspecified broods were also reared in several other years and there are in existence several clutches of eggs taken from this locality during the same period. The haunt was never known to be deserted between 1910 and 1939, and the only cause of breeding failure was egg collecting, apart from one year in which the birds deserted after being kept off the nest for many hours. At least two different females were involved during this period.

The recent history of occupation at this same haunt is as follows:—

1961 3 eggs; two were later broken, the third hatched but the chick died.

1962 3 eggs; all disappeared later, evidently through parental destruction.

1963 3 eggs; one taken fresh for chemical analysis (Table IIB, 1963, No. 3), the other two hatched; one chick died and the other fledged.

1964 3 eggs; only one chick hatched and it later died.

1965 3 eggs; one broken later, one bad (Table IIB, 1965, No. 4) and the third hatched; the single chick fledged.

1966 No trace of the birds.

While the two eggs containing total organochlorine residues of 36 and 27 p.p.m. (dieldrin+heptachlor epoxide 5.2 and 1.4 p.p.m.) were from clutches from which single young were fledged, this level of contamination was associated with a marked reduction in brood size, compared with pre-war years. This haunt was one of only five (out of 30) once regularly occupied territories in Northern England which were continuously occupied throughout the period 1960–65; and 1966 was the first year since 1910 when Peregrines were absent. Probably the same female occupied the haunt from 1961 to 1965, but it was a different bird from that present in 1939.

The summarised figures in Table I conceal the details of change occurring within a population which as a whole remains stable. For instance, in Southern Scotland, 27 territories were visited in both 1965 and 1966, and 16 were found occupied in each year, but only 13 were occupied in *both* years. Since 1960, it is usual for this region and Northern England to show small gains and losses in any year, by comparison with the preceding and succeeding years, so that fresh gaps are still appearing as old ones are filled.

The output of young Peregrines annually from the whole of the Scottish Highlands would seem adequate to allow a slow receovery, at least in occupation of territories, and it is perhaps surprising that even in this region, about 47 per cent of territories visited remained deserted or held by non-breeders in 1966. However, the annual surplus has also to fill gaps caused by mortality amongst the established breeding population, and when birds move away from their birthplace to depleted areas, they are themselves increasingly exposed to pesticidal contamination, with the implication of increased risks of mortality and breeding failure. As not all Peregrines are likely to reach sexual maturity at one year old, many probably pass their juvenile stage in country away from breeding haunts and may then be more at risk, as regards pesticides, than if they were able to occupy a nesting place in their first year.

Walpole-Bond (1914) noted that a barren female Peregrine refused to mate or to allow a prospecting pair to settle on her breeding cliffs, but after she was shot, a new pair soon appeared and nested. It could be that many of the non-breeding Peregrines recently holding territories also defend them against potential breeders which arrive from other area. Cade (1960) has suggested that the tenacity with which Peregrine eyries are

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usually held over a long period depends on the survival at all times of one bird of the occupying pair, and that when both of the pair die simultaneously, continuity is lost and the haunt may then be left deserted for a period. Many Peregrine breeding haunts south of the Highlands seem to have been totally deserted for several years, and this loss of continuity may be an additional factor working against their re-occupation. Even so, rate of re-occupation of totally deserted haunts in Southern England was fairly rapid after intensive human 'control' ceased in 1945. The continued failure of the Peregrine to restore its previous breeding numbers is most likely to be explained by lack of improvement in the adverse factor which originally depleted the areas concerned.

CONCLUSIONS

The continued investigations of 1965–66 reinforce earlier conclusions (Ratcliffe 1963, 1965) that the persistent organo-chlorine pesticide residues have been a causal factor in the post-1955 decline of the Peregrine in Britain. In view of the evident maintenance of contamination levels in the environment, it is not surprising that the breeding population has shown no clear tendency towards recovery. Moreover, there would seem to be no sign of general resistance to these chemicals developing in this species.

SUMMARY

A sample census of about one-third of the Peregrine breeding population of Great Britain in 1965 and 1966 indicates that there has been no significant change in proportion of occupied territories or breeding success of remaining birds during this period.

Comparison with earlier data suggests that the Peregrine decline ceased after 1963, and that the population has since remained relatively stable, with occupied territories at about 40 per cent of the pre-war level and breeding success (pairs rearing young) varying between about 13 and 16 percent of the maximum possible level (former mean annual number of pairs). Breeding success may have improved marginally after 1963 on the national scale, and more significantly in Southern Scotland and Northern Ireland.

The geographical pattern is unchanged, with population level, breeding success and brood size lowest in England and Wales, and highest in the South and East Highlands of Scotland.

Analysis of Peregrine eggs gives no evidence of a decrease in contamination by any organo-chlorine residue since 1964. Eggs from Northern England and Southern Scotland were more heavily contaminated than those from the South and East Highlands during the period 1963–66, though the difference lies mainly in the DDE component.

Failure of young Peregrines from successful eyries to build up the breeding population of depleted areas is probably a reflection primarily on the lack of improvement in the adverse factor which initiated decline.

ADDENDUM

Since this account was written, preliminary data for 1967 have become available. They indicate a slight recovery of population, in both occupation of territories and breeding success, in the east and central Scottish Highlands, Northern England and Northern Ireland. In the southwest Highlands and Southern Scotland, breeding success was lower than in 1966, but there was no decrease in number of occupied territories. Analysis of ten eggs in 1967 shows a decrease in organo-chlorine residue levels, especially of dieldrin and heptachlor epoxide, compared with 1963–66, and also confirms that residue levels are significantly lower in the Central Highlands than in other regions of the south. Slight recovery of the population in more northerly regions is thus consistent with a decrease in environmental contamination, at least in these more marginal arable farming districts, which were least affected by the original population decline.

It has recently been shown (Ratcliffe 1967) that the post-war prevalence of egg breaking in the British Peregrine correlates closely with a widespread decrease in eggshell weight/size ratio (i.e. probably thickness) which appeared in 1947 and has persisted ever since, except in some parts of the Central Highlands. The connections between these phenomena, and their possible relationships to contamination of the species by organo-chlorine residue, are being examined.

PROBLEMS WITH DDT IN FISH CULTURAL OPERATIONS

(J. P. Cuerrier, J. A. Keith, and E. Stone)

ABSTRACT

Various concentrations of DDT and residues have been detected in eggs and fry of speckled, rainbow, and cutthroat trout obtained from local sources and from commercial suppliers and handled at the Maligne River Trout Hatchery, Jasper National Park, Alberta. Concentrations of DDT and metabolites exceeding 400 ppb in eggs resulted in a 30 to 90 per cent mortality among the fry 60 fingerlings during the days following the swim-up stage. All commercial dry feeds analysed contained DDT. Among ingredients used in the manufacturing of trout feeds, only brewer yeast was found almost free of contamination.

INTRODUCTION

Because of the very wide distribution of DDT, it would seem that all forms of life are being exposed, directly or indirectly, to this chemical insecticide. Extensive research has been done on the toxicity of DDT to insects, the primary target, but comparatively little is known of the effects of secondary contamination of animals, particularly during the very early stages of development. The purpose of this paper is to present data on DDT contamination of trout in fish hatcheries.

Mack and co-workers (1964) found DDT concentrations in whole fish ranging from 0.2 to 7 ppm; certain tissues or organs contained up to 40 ppm. Burdick and co-workers (1964) found as much as 500 ppm of DDT by weight in ether-extracted oils from lake trout eggs taken from Lake George, New York State. They found that 90 percent of lake trout [illegible] containing 2.96 ppm of DDT and above died at the fry stage. With landlocked salmon at Sebago Lake, Maine, Anderson and Everhart (1966) found that ovaries of three-year-old salmon contained 0.87 ppm of DDT, while ovaries of older salmon showed 6.0 ppm of DDT.

Mortality at the yolk-sac stage of lake trout in George Lake and other waters in the State of New York, and of the landlocked salmon in Sebago Lake, has been ascribed to DDT contamination.

For many years, gill diseases were thought to cause mortality at different stages of development of the various trout species raised at the Maligne River Trout Hatchery, Jasper National Park, Alberta. Recent investigations by the Pathology Section of the Canadian Wildlife Service, with the co-operation of the U.S. Bureau of Sport Fisheries and Wildlife, have revealed the occurrence of such diseases as "cold-water disease", infectious pancreatic necrosis, and "kidney disease", in addition to gill diseases. Mortality has also been caused by dissolved copper and zinc from pipes and valves in the hatchery. In spite of these hazards and the Damocles' sword ever present in fish culture operations, in 1966 the Maligne River Hatchery produced more than one and one-half million trout of various species and sizes for plantings in the Mountain Park waters.

However, some mortality could not be explained by viral or bacterial infections and DDT contamination was suspected. Samples of eggs, alevins, and commercial dry foods were analysed. All analyses were performed under contract by Dr. D. J. Ecobichon, Pharmacology Division, University of Guelph, using electron capture gas chromatography and the extraction procedure of Saschenbrecker and Ecobichon (1967).

TROUT EGGS AND ALEVINS

Trout eggs handled at the Maligne River Trout Hatchery come from various sources: (a) local collections from wild stocks originating from annual hatchery plantings; (b) local collections from domestic stocks held at the hatchery; (c) commercial suppliers located in the United States; and (d) provincial and federal fisheries agencies. Table 1 presents data on DDT and metabolite levels found in eggs and alevins of various species of trout.

In view of the preliminary and exploratory nature of this report, no attempt is being made to establish a relationship between the levels of each type of residue found in the various samples. However, in samples with levels of total DDT and residues below 200 ppb, residues of DDT and metabolites appear in the following order: the lowest levels are of o,p'-DDT, followed by DDD,, p-p'-DDT, and DDE. DDE was the major component, with about twice as much of it as of the other residues combined.

TABLE 1.—DDT AND METABOLITES IN PARTS PER 10^9 (PPB) WET WEIGHT IN EGGS AND FRY OF VARIOUS SPECIES OF TROUT

Sample catalog	Description[1]	Concentration in parts per 10^9, ppb, wet weight					Losses[2] (percent)
		DDE	o,p'-DDT	DDD	p,p'-DDT	Total	
B-477	RT eggs, wild, Jasper	65	8	23	25	123	—15
B-479	RT eggs, commercial	57	19	28	44	148	—15
B-480	RT eggs, commercial	63	29	33	53	178	
B-726	RT eggs, commercial	79	(3)	(3)	(3)	79	
B-727	RT eggs, commercial	129	(3)	26	21	176	
B-728	RT eggs, commercial	46	(3)	11	7	64	
B-729	RT eggs, commercial	62	(3)	6	(4)	68	
B-730	Cutth. T. eggs, domestic	166	(4)	378	23	567	30
B-420	EBT domestic, fry	333	44	(3)	87	464	70
B-417	RT f.sp., yolk fry	1,022	54	294	52	1,422	90
B-418	RT f.sp., yolk fry	971	(4)	178	(4)	1,149	90
B-478	EBT fry, domestic	217	16	51	201	485	90

[1] Abbreviations: RT equals rainbow trout; f.sp. equals fall spawning; EBT equals eastern brook or speckled trout; Cutth T. equals cutthroat trout.

[2] Losses during the 2-month period following the swim-up stage.

[3] Indicates undetected, the limit of detection being 1 ppb.

[4] Indicates traces in the range of 1 to 5 ppb.

Eggs collected from wild rainbow trout in Lake Edith, Jasper National Park, where annual plantings are carried out, showed a total level of 123 ppb of DDT and metabolites. Losses during the 60 days following the swim-up stage were less than 15 per cent. Spring-spawning rainbow trout eggs from commercial sources contained levels ranging from 64 ppb to 178 ppb. Losses in alevins from these eggs were less than 15 per cent during the 60 days following the swim-up stage. Losses of this magnitude are considered normal for that stage. However, cutthroat trout fry resulting from eggs purchased from a commercial supplier showed a total concentration of 567 ppb of DDT and metabolites; losses were about 30 percent.

Eastern brook trout fry resulting from eggs

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extracted from a domestic brood stock held at the Jasper Hatchery had a mortality of 70 per cent. The total level of DDT and metabolites was 464 ppb.

Rainbow trout yolk-sac fry from an autumn-spawning strain obtained from a commercial supplier contained 896 ppb of DDT and 236 ppd of DDD for a total of 1,285 ppb of DDT and metabolites. Losses amounted to close to 90 per cent in the two-month period which followed the swim-up stage. Similar heavy losses were experienced with brook trout fry resulting from eggs obtained from a domestic brood stock held by a government agency. The concentration of total DDT and metabolites was 485 ppb, mostly DDE and p.p'DDT.

The fish with high levels of mortality were not exposed to disease more than the others, but during the period of this study, mortality above 25 per cent seemed to be associated with comparatively high levels of DDT and its metabolites. Therefore, we conclude that insecticide residues were responsible for this high mortality. In their paper on chronic effects of DDT on cutthroat trout, Allison and coworkers (1964) stated that "there was a critical period shortly after hatching when mortality was noticeably higher in offspring of the high-dosage lots".

The relationship between mortality, level of DDT contamination of the eggs, and temperature of the water during yolk-sac absorption is under experimental study. Incubation and hatching during the winter and spring seasons at the Maligne River Trout Hatchery take place at a water temperature of 40° F. Brook trout fry and alevins which experienced a 90 per cent mortality at our Maligne River Trout Hatchery had less than 15 per cent mortality at the hatchery where the eggs came from. At that establishment, incubation of trout eggs is carried out at a water temperature ranging from 32° F. to 36° F.

COMMERCIAL TROUT DRY FEEDS

Fry are fed with commercial dry feeds after reaching the advanced swimup stage. Samples of dry feeds were analysed. Results are presented in Table 2 but for obvious reasons, brand names and sources are not given. Analyses revealed the presence of DDT in all samples, with levels ranging from 2 ppb to 234 ppb. One sample also contained 17 ppb of dieldrin.

Presence of metabolites, from low to high levels, is as follows: *o,p'*-DDT, DDD, *p,p'*-DDT, and DDE. This same order was observed with the samples of rainbow trout eggs with low levels of DDT and metabolites. Some ingredients utilized in the manufacturing of dry feeds were analysed for DDT residues. Data obtained indicated that of all the ingredients examined, only brewers' yeast contained residues no higher than 5 ppb; soybean meal and fish meal contained less than 100 ppb.

TABLE 2.—DDT AND METABOLITES IN PARTS PER 10^9 (ppb) WET WEIGHT IN MANUFACTURED DRY FEEDS FOR TROUT

Sample catalog number	Concentrations in parts per 10^9, ppb				
	DDE	o,p'-DDT	DDD	p,p'-DDT	Total
473–476	104	27	38	65	234
483–476	45	19	42	54	160
491–493	45	35	38	78	196
B–1348	71	(1)	33	46	150
B–1349 [2]	59	(1)	20	28	107
B–1351	75	(1)	67	54	196
B–1352	56	(1)	47	39	132
B–1456	44	(1)	96	74	214
B–407	2	(1)	(1)	2	4
B–408	2	(1)	(1)	2	4
B–490	16	(1)	(1)	(3)	16
B–723	19	(1)	26	9	54
B–724	33	50	67	238	388
B–1166	125	126	249	157	657
B–1456	44	(1)	96	74	214
B–146	60	(1)	67	24	151

[1] Indicates undetected, the limit of detection being 1 ppb.
[2] This feed also contained 17 ppb dieldrin.
[3] Indicates traces in the range of 1 to 5 ppb.

CONCLUSION

Various levels of DDT and residues have been found in brook, rainbow, and cutthroat trout handled at the Maligne River Trout Hatchery in Jasper National Park. When levels of DDT and metabolites exceeded 400 ppb in eggs, mortality in the resulting fry ranged from 30 per cent to 90 per cent in the 60-day period following the swim-up stage. All commercial dry trout feeds analysed were found to contain chlorinated hydrocarbons. Of several ingredients used, only brewers' yeast was found to be almost free of contamination.

From operational observations, it would seem that DDT in manufactured trout food is detrimental to the growth of trout raised under hatchery conditions, when DDT and metabolites in the eggs and fry exceed certain levels.

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Chlorinated Hydrocarbons and Eggshell Changes in Raptorial and Fish-Eating Birds

(Abstract. Catastrophic declines of three raptorial species in the United States have been accompanied by decreases in eggshell thickness that began in 1947, have amounted to 19 percent or more, and were identical to phenomena reported in Britain. In 1967, shell thickness in herring gull eggs from five states decreased with increases in chlorinated hydrocarbon residues.)

New perspectives on the role of chlorinated hydrocarbon insecticides in our environment have come into focus in recent years. Successive discoveries have demonstrated that these compounds are systematically concentrated in the upper trophic layers of animal pyramids (1). Raptorial bird populations have simultaneously suffered severe population crashes in the United States and Western Europe (2, 3, 4). These involve reproductive failures which, at least in Britain, are characterised by changes in calcium metabolism and by a decrease in eggshell thickness resulting in the parent birds' breaking and eating their own eggs (4, 5, 6). Such a derangement of calcium metabolism or mobilization perhaps could result from breakdown of steroids by hepatic microsomal enzymes induced by exposure to low dietary levels of chlorinated hydrocarbons (7).

We have examined the possibility that the eggshell changes reported in Britain (6) have also occurred in the United States and that the raptor population crashes in Europe and North America may have had a common physiological mechanism. The population changes are without parallel in the recent history of bird populations (8). They include the pending extirpation of the peregrine falcon *(Falco peregrinus)* in northwestern Europe, the complete extirpation of the nesting population of this species in the eastern half of the United States, and simultaneous declines among other bird- and fish-eating raptors on both sides of the Atlantic.

We examined 1729 blown eggs in 39 museum and private collections. Shells were weighed to the nearest hundredth of a gram. In 29 percent of these, we were able to insert a micrometer through the hole drilled by the collector at the girth of the shell and to take four measurements of thickness 7 mm from the edge of the blow hole; these were then averaged to the nearest 0.01 mm for each shell. Thickness in each case then represented the shell itself plus the dried egg membranes. Peregrine falcons, bald eagles *(Haliaeetus leucocephalus)*, and ospreys (*Pandion haliaetus*) were selected as having one or more regionally declining populations; golden eagles *(Aquila chrysaetos)*, red-tailed hawks *(Buteo jamaicensis)*, and great horned owls *(Bubo virginianus)* were selected as representative of reasonably stationary populations that may be slowly declining as their habitats are gradually destroyed by man, but for which widespread reproductive failures are currently unknown. In addition, 57 eggs of the herring gull *(Larus argentatus)* were collected from five colonies in 1967. The shells of these were dried at room temperature for 4 months before being measured, and residues of the entire egg contents were analysed by the Wisconsin Alumni Research Foundation for chlorinated hydrocarbons but not for polychlorinated biphenyls. Analytical procedure followed that outlined by the U.S. Food and Drug Administration *(9)*. Analyses were conducted on a gas chromatograph (Barber Coleman, model GC 5000, and Jarrell-Ash, model 28-700) with electron-capture detectors. The glass column (0.6 cm by 1.2 m) was packed with 5 percent DC 200 (12,500) on Cromport XXX. The column temperature was 210°C, and the nitrogen flow rate was 75 cm^3/min. Each portion of the ground and dried samples was extracted for 8 hours or more in a Soxhlet apparatus with a mixture of ether and petroleum ether (70:170). Portions of the extracts were further purified by putting them through a Florisil column.

In California, where the peregrine falcon population is in "a serious condition" *(10)*, a change of 18.8 percent in shell weight occurred from 1947 to 1952. Ratcliffe (6) found a corresponding decrease of 18.9 percent in Britain. The change in California involved a decrease in shell thickness and had no precedent in the previous 57-year recorded history of the peregrine in that state (Fig. 1). In the eastern United States, where the nesting population of peregrines has now been wiped out *(2)*, fragmentary data indicate that the same change took place (Table 1). Broken eggshells in a North American peregrine eyrie were observed for the first time in 1947 by J. A. Hagar 60 miles (6.9 km) from the Massachusetts eyrie cited in this table *(11)*. They were next inferred in Quebec in 1948 when egg-eating was observed at the same site in 1949 *(12)*, and were observed in Pennsylvania in 1949 and 1950 *(13)*. Chlorinated hydrocarbon data for this now-extinct regional population are completely absent. For nine surviving adult peregrines in Canada's Northwest Territories in 1966, the data are reported to have averaged 369 parts per million (ppm) (fresh weight) in fat *(14)*. For four adults in another migratory population in northern Alaska, values were even higher *(15)*.

For the five other raptorial species we have studied, the data do not permit a precise delineation of the onset of the change in calcium metabolism or mobilisation, but the decrease (Table 1) in shell weight (and hence thickness) has involved only declining populations and not stationary ones. Change in shell thickness occurs in poultry as a result of dietary deficiencies and age *(16, 17)*. This phenomenon would probably

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not occur simultaneously on two continents 1 year after the chlorinated hydrocarbon insecticides came into general usage. Other chemicals affect shell thickness in poultry *(17)*, but the finding of high concentrations of chlorinated hydrocarbons in the eggs of wild populations of raptors and the time correlation of shell changes with the introduction of DDT [1,1,1-trichloro-2,2,-bis (*p*-chlorophenyl) ethane] tend strongly to suggest that chlorinated hydrocarbons are the major contributing cause, although it is not unlikely that other chemicals could be contributory.

TABLE 1.—WEIGHTS OF RAPTOR EGGSHELLS IN MUSEUM AND PRIVATE COLLECTIONS

Region	Period	Number	Weight (g) Mean±S.E.[2]	Weight (g) Change (percent)	Population trend (or reproduction)
Red-tailed hawk: California (23)[1]	1885–1937	386	6.32±0.032		
	1943–44	6	6.09±0.237	−3.6	Stationary.
	1953–67	8	6.49±0.214	+2.7	Do.
Golden eagle: California (23)	1889–1939	278	13.03±0.083		
	1940–46	28	12.70±0.161	−2.5	Do.
	1947–65	33	13.41±0.232	+2.9	Do.
Bald eagle (24a):					
Brevard County, Fla.	1886–1939	56	12.15±0.127		
	1947–62	12	9.96±0.280	−18.0	Declining.
Osceola County, Fla.	1901–44	25	12.32±0.240		
	1959–62	8	9.88±0.140	−19.8	Do.
Osprey (24b):					
Maryland-Virginia	1890–1938	152	7.05±0.054		
	1940–46	21	6.91±0.164	−2.0	Stationary.
	1955	3	6.85	−2.8	Do.
New Jersey	1880–1938	117	7.08±0.069		Do.
	1957	6	5.30±0.446	−25.1	Declining.
Peregrine (25):					
British Columbia	1915–37	29	4.24±0.061		
	1947–53	15	4.18±0.081	−1.4	Stationary.
California (23)	1895–1939	235	4.20±0.031		
	1940–46	49	4.07±0.038	−3.1	No data.
	1947–52	31	3.41±0.084	−18.8	Declining.
New Hampshire to New Jersey[3]	1888–1932	56	4.38±0.034		
Vermont	1946	3	4.30	−1.8	Stationary.
Massachusetts	1947	3	3.47	−20.8	Extirpated.
New Jersey	1950	3	3.24	−26.0	Do.
Great horned owl:					
California (23)	1886–1936	154	4.50±0.033		
	1948–50	12	4.62±0.119	+2.4	Stationary.

[1] Citations (23–25) refer to the data for the population trend.
[2] S.E., standard error of the mean.
[3] Including Vermont and Massachusetts.

In order to test the hypothesis that these recent changes of thickness in raptor eggshells were the result of differences in exposure to chlorinated hydrocarbons we analysed 10 to 14 eggs taken in 1967 from each of five colonies of the herring gull *(Larus argentatus)*. Mean shell weight and thickness in 55 eggs collected in the same five states prior to 1947 disclosed no geographic gradients or significant differences. The 1967 mean thicknesses for each colony were therefore compared to mean levels of residual DDE [1,1-dichloro-2,2-bis (*p*-chlorophenyl) ethylene] on a fresh-weight basis, with the result shown in Fig. 2, the *r* value being significant, with P = .001. The residues of polychlorinated biphenyls *(18)* have not been studied in these ecosystems, but DDE has been consistently high in the Lake Michigan birds, averaging (fresh weight) 1925 ppm (S.E. 274) in the fat of 12 healthy adults collected in 1963–64 *(19)*.

Reproduction in these gull colonies was generally normal in 1967 except perhaps in Wisconsin. At the latter colony where an 11 percent mean decrease in shell thickness occurred, some egg breakage and shell flaking was evident in 1967, although not at the frequency seen in previous years. Excessive reproductive failure occurred at this site in 1964 when about 18 percent of eggs lost about one-third of the shell due to flaking, when clutch size decreased and embryonic mortality was high, and when DDE residues averaged 202 ppm (S.E. 34) in nine eggs *(20)*. (If linear extrapolation of the 1967 values is carried out to 202 ppm, the shell thickness in 1964 could be estimated as having decreased by about 32 percent.) The effectiveness of DDE in the enzymatic metabolism of aminopyrine has been reported by Hart and Fouts *(21)*, and our data suggest that this compound, because of its prevalence, has played a major role in inducing the hepatic microsomal metabolism of steroids that in turn resulted in the eggshell changes we have encountered in museum collections. Without doubt DDE is the commonest insecticide or insecticide analog now being found in avian tissues *(22)*. In 1966, it was found to average 284 ppm (S.E. 62) in the fat of nine arctic-breeding peregrine falcons *(14)* and about 414 ppm in four others on a wet-weight basis *(15)*. Concentrations of this compound and other chlorinated hydrocarbons in the peregrine populations that crashed farther south can be assumed to have been as high—and they may have been much higher.

From the above evidence and that accumulated by others *(2, 4, 6, 8)*, we have reached these conclusions: (i) many of the recent and spectacular raptor population crashes in both the United States and Western Europe have had a common physiological basis; (ii) eggshell breakage has been widespread but largely overlooked in North America; (iii) significant decreases in shell thickness and weight are characteristic of the unprecedented reproductive failures of raptor populations in certain parts of the United States; (iv) the onset of the calcium change 1 year after the introduction of chlorinated hydrocarbons into general usage was not a random circumstance; and (v) these persisting compounds are having a serious insidious effect on certain species of birds at the tops of contaminated ecosystems.

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DANIEL W. ANDERSON,
Department of Wildlife Ecology, University of Wisconsin, Madison.

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25. Except for the California data *(23)* the data on population trends are given in *(8)* by F. L. Beebe for British Columbia; by W. R. Spofford for Vermont; by J. A. Hagar for Massachusetts; and by D. D. Berger *et al.* for New Jersey.

26. Research carried out under contract with the Bureau of Sport Fisheries and Wildlife, Fish and Wildlife Service, U.S. Dept. of Interior. W. H. Drury, J. T. Emlen and M. E. Slate provided gull eggs for analysis. E. N. Harrison, W. C. Hanna, and many other zoologists greatly facilitated our measurements of eggshells. We thank D. A. Ratcliffe for advice throughout the entire study.

16 July 1968

Mr. PROXMIRE. Mr. President, I have an amendment at the desk and I ask that it be stated.

The PRESIDING OFFICER. The amendment will be stated.

The ASSISTANT LEGISLATIVE CLERK. The Senator from Wisconsin proposes an amendment, on page 73, line 24, insert the following new section:

> SEC. 109. Section 1705 (h) of Public Law 90-448 is amended by striking the word "or" where it appears before the word "domitory" and by inserting after the word "domitory" the following: ", water, or sewer".

Mr. PROXMIRE. Mr. President, the Water Quality Improvement Act of 1969 which the Senate is considering today is mainly concerned with the control of pollution whether by oil, sewage flow, acid mine drainage, or related pollutants into our rivers and harbors. This bill would authorize appropriations to alleviate polluted [p. 29007] conditions and to provide for better coordination between Federal, State, and local water pollution control programs. I congratulate the distinguished Senator from Maine for the excellent leadership he has shown on environmental policy. His work on the Water Quality Improvement Act is but one example of his continuing efforts over the years to combat air and water pollution.

I understand that the Public Works Committee will later consider legislation on the very important subject of providing additional financing to State and local governments for the construction of needed water and sewer facilities. In 1968, State and local governments borrowed nearly $3 billion to provide capital for financing water, sewer, and conservation programs. The Water Quality Improvement Act of 1968 was passed by the Senate, but was not enacted into law because time ran out in the 90th Congress before differences in the House and Senate versions could be resolved. This 1968 act would have enabled State and local government units to raise between $6 and $7 billion in capital by means of municipal bond issues in order to pay for needed construction.

The amendment I offer today would afford to the State and local government units access to the capital market now enjoyed by State and local governments when they issue bonds for housing, university, and dormitory purposes. Having access to a competitive capital market will enable the State and local governments throughout the country to borrow money for water and sewer construction at the lowest possible cost. It is my belief that in view of the astronomically high interest rates which are now being paid, it is more imperative that new water and sewer construction be paid for by raising capital under the most advantageous conditions. Furthermore, as I mentioned earlier, the fact that the Public Works Committee has not yet considered legislation relating to financial assistance by the Federal Government for the raising of such capital is an additional reason why it is important at this time that every advantage of a competitive market be given for State and local borrowing for water and sewer needs.

Mr. President, the Committee on Banking and Currency has considered this amendment in some detail and hearings have been held on it. The Senator from Maine (Mr. MUSKIE) is familiar with the action taken, as he serves as a member on that committee. It has also been discussed on the floor before, and I would hope, as it is discussed now with the distinguished Senator from Maine, that he will be able to accept the amendment.

Mr. MUSKIE. Mr. President, I support the adoption of the amendment offered by my distinguished colleague from Wisconsin. The Subcommittee on Air and Water Pollution has given considerable thought and study as to how capital is to be available to our hard-pressed States and cities for the construction of waste treatment facilities. I believe that every Member of Congress is aware of the acute need in every State and community for such facilities. Many different financing proposals have been considered by the subcommittee and by the full Public Works Committee. The Clean Water Restoration Act of 1966 authorized $3.5 billion for substantial Federal grants for this purpose. However, appropriations have fallen far short of the authorized amounts. This situation will be partially rectified this year if the Congress appropriates the amounts included by the House Appropriations Committee in the Public Works appropriations bill.

In the meantime, State and local government units have continued to raise the capital for both their share and the Federal share of a project cost by the issuance of bonds. They will continue to raise needed State and local capital by this method in the future. The amendment now under consideration would enable the public issuers to have access to the same capital markets now available for Federal financing thereby insuring that they may borrow in a competitive market at the lowest cost.

Mr. President, for many reasons the amendment is thoroughly consistent with the objectives of the committee, struggling against budgetary restrictions over the past 3 or 4 years, to find alternative ways to make it possible for States and communities to find the capital to build these facilities.

I compliment the Senator for offering his proposal. It has been heard by committees. It is demonstrably sound on the basis of the hearings held, and I am delighted to take the amendment into the bill.

The PRESIDING OFFICER. The question is on agreeing to the amendment offered by the Senator from Wisconsin.

The amendment was agreed to.

Mr. MUSKIE. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. BYRD of West Virginia. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

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1.18a(4)(c) VOL. 115 (1969), Oct. 8: Passed Senate, p. 29099

[No Relevant Discussion on Pertinent Section]

1.18a(4)(d) VOL. 116 (1970), March 24: Senate agrees to conference report, p. 4424

[No Relevant Discussion on Pertinent Section]

1.18a(4)(e) VOL. 116 (1970), March 25: House agrees to conference report, p. 9334

[No Relevant Discussion on Pertinent Section]

1.18b FEDERAL WATER POLLUTION CONTROL ACT AMENDMENTS OF 1972

October 18, 1972, P.L. 92-500, § 104(e), 86 Stat. 822

AN ACT

To amend the Federal Water Pollution Control Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Water Pollution Control Act Amendments of 1972".

SEC. 2. The Federal Water Pollution Control Act is amended to read as follows:

"TITLE I—RESEARCH AND RELATED PROGRAMS

* * * * * *

SEC. 104

* * * * * *

"(l) (1) The Administrator shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than January 1, 1973, develop and issue to the States for the purpose of carrying out this Act the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

1.18b(1) SENATE COMMITTEE ON PUBLIC WORKS

S. REP. No. 92-414, 92d Cong., 1st Sess. (1971)

FEDERAL WATER POLLUTION CONTROL ACT AMENDMENTS OF 1971

OCTOBER 28, 1971.—Ordered to be printed

Mr. RANDOLPH, from the Committee on Public Works, submitted the following

REPORT
together with

SUPPLEMENTAL VIEWS
[To accompany S. 2770]

The Committee on Public Works, to which was referred the bill (S. 2770) Federal Water Pollution Control Act Amendments of 1971, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass. An original bill (S. 2770) is reported in lieu of S. 523, S. 1012, S. 1013, S. 1014, S. 1017 and S. 1238 which were considered by the committee.

[p. 1]

DISCUSSION OF INTENT

TITLE I—RESEARCH AND RELATED PROGRAMS

Section 104—Research, Investigations, Training, and Information

The authority of the Administrator in support of research programs to prevent and eliminate water pollution is continued and expanded.

The Administrator is authorized to establish field research laboratories in six sections of the Nation and to study the nature of river systems and sewage in rural areas. Authorization for a one-year study of problems associated with the disposal of waste oils, such as lubricating oils, is included in this section.

New authorizations in this section also provide for research into means to reduce unnecessary water consumption, as well as research, in cooperation with the Secretary of Agriculture, on problems associated with the control of agricultural pollution. Ten million dollars is authorized in fiscal year 1972, and annually thereafter, for this agricultural pollution research.

Another $7,500,000 is authorized in fiscal year 1972 to continue a pilot training program for personnel to operate and maintain treatment works. In fiscal year 1972 $2,500,000 is authorized to continue work on the forecasting of employment needs in water pollution control. In addition to such special authorizations, there is a general authorization for this section of $65,000,000 in fiscal year 1972, $70,000,000 in fiscal year 1973, $75,000,000 in fiscal year 1974, and $80,000,000 in fiscal year 1975. [p. 13]

Water pollution resulting from agricultural production is clearly a growing problem of great magnitude and complexity. Agriculture is now one of the major contributors to the degregation of the quality of our navigable water. The basic problem is one of managing the inputs and outputs of agricultural production to maintain the quality of the water, air, and soil environment while economically producing food and fiber.

Progress has been made in agricultural research but we must go beyond it to meet the present challenge. Until we compile adequate identification, analysis, and evaluation of existing programs and methods; vigorously study alternative production decisions available to [p. 15] agricultural producers at various steps of the production process; and develop information of about the social, legal, and economic impacts of these methods, we will have little impact on the enormous problem of agricultural water pollution.

Subsection (p) provides that the Administrator shall carry out a comprehensive study and research program to determine new and improved methods of preventing and controlling water pollution from agriculture, including legal, economic, and other implications of the use of such methods.

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SUPPLEMENTAL VIEWS OF SENATOR BOB DOLE

The bill reported by the committee adopts many of the proposals offered by the President in his February 10, 1971, environmental message and has been developed through a long process of consultation and discussion between the committee and the administration.

A major new thrust of this bill is in the field of agricultural pollution, and as a Senator from an agricultural State and a member of the Senate Agriculture Committee, this matter is of great interest to me and my State.

The bill would amend the Federal Water Pollution Control Act to place responsibility on the States for instituting and expanding the control of water pollution related to agriculture. To assist the States in this effort, the Environmental Protection Agency, working closely with the Department of Agriculture, is directed by the bill to provide technical expertise and in some cases financial assistance for combatting this serious, yet extremely complex, form of pollution. A total of $10 million is provided for agricultural research.

This bill recognizes that the U.S. Department of Agriculture and the agricultural community in general have made great strides in improving the quality of the environment; therefore, the bill does not attempt to parallel or duplicate the contributions already made but seeks to incorporate them into the framework of the act.

The committee report discusses the operative provisions of the bill in considerable detail and describes some of the problems associated with agricultural pollution. Since this is a new area for pollution control legislation, I would like to discuss some of the more important aspects of this area which lie within the scope of the bill's operations.

Agricultural pollution control is concerned primarily with the following:

Sedimentation
Animal wastes
Fertilizers
Pesticides, Fungicides and Herbicides
Forest and crop residues

Agricultural processing wastes
Inorganic salts and minerals

The management and control of these factors are essential to the maintenance of environmental quality while providing food and fiber products in abundant quantity. At the outset, I believe it is important to recognize that we are undertaking the first step in establishing an overall water pollution control system. Before solutions can be effected, we must, first identify and define the problems which face us, and second, we must then take into account the available means of control and the costs of each type of control.

I believe discussion of three specific problem areas—pesticides, animal wastes and fertilizers—will be helpful in understanding the complexity of the agricultural problem and at the same time indicate the need for coordinated control programs.

Most of the problems of agricultural pollution deal with non-point sources. Very simply, a non-point source of pollution is one that does not confine its polluting discharge to one fairly specific outlet, such

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as a sewer pipe, a drainage ditch or a conduit; thus, a feedlot would be considered to be a non-point source as would pesticides and fertilizers.

PESTICIDES, HERBICIDES AND FUNGICIDES

Pesticides provide substantial benefits to mankind by protecting plants and animals from pest losses. It has been estimated that without pesticides, food production would be reduced by 40 to 50 percent, with substantial accompanying reductions in quality also.

Approximately 50,000 species of fungi cause more than 1,500 plant diseases; of about 30,000 species of weeds 1,800 cause serious economic losses each year; and nearly 1,500 varieties of nematodes cause significant damage. In addition, there are more than 10,000 species of insects capable of causing large losses in food, feed and fiber production. A number of agricultural chemicals are used to control these problems, and their ecological impact must be taken into account in the formulation of agricultural production programs.

The chief hazard of pesticide use lies in the long-lasting properties possessed by many of them. Some, such as DDT, retain their potency for virtually unlimited periods after application, their residues are introduced into the complicated food chains at work in nature, and, ultimately, they become concentrated at levels which are hazardous to both animal and human life.

Pesticide residues are of concern in three ways. First, residues become attached to soil particles and may reach water through runoff and erosion. Second, some crops pick up and accumulate excess residues when irrigated with water contaminated through runoff erosion.

Third pesticide residues in water are picked up at low levels by certain marine organisms which result in relatively high concentrations being reached in organisms at the top of the food chain.

The use of pesticides and other agricultural chemicals will undoubtedly retain a high level of importance in agriculture for the foreseeable future. In the meantime efforts at both State and Federal levels are paying off in securing the registration and adherence to recommended usages. Increased research is underway to develop alternative means of pest, weed and fungal control. Experiments are underway to develop integrated programs in which cultural, mechanical, chemical and biological methods are combined to achieve the greatest degree of control at the least expense to the environment.

Every possible effort must be made to see that in achieving control appropriate chemicals are applied at carefully controlled minimum rates. Off-target applications must be reduced, and soil and water conservation measures must be utilized to prevent movement of chemicals through runoff and erosion.

The ideal solution to the problem of pesticide residues would be to employ only pesticides which degrade after application and leave no toxic or hazardous after-products. The difficulty in this solution, however, appears to be that the available alternative chemicals which are non-persistent are extremely toxic to human life in the forms in which they are effective in pest control.

Immediate dangers to human life are posed by these extremely toxic chemicals, such as parathion which has been recommended as a substitute for DDT. These substances, commonly referred to as "hot" chem-

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icals, are recommended for use because they do attack the pests against which persistent chemicals have proven effective, but they do not persist in their toxic state for long periods after application. Shortly after application, these chemicals start to disintegrate and are soon absorbed by natural processes leaving no residual accumulation to endanger wildlife or man. The difficulty in their use arises out of their high original toxicity. These chemicals cause most of the deaths from pesticides in the Nation. Mere exposure to dust from a parathion sack has resulted in the death of children, and farmers, justifiably, are fearful to use these "hot" chemicals.

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1.18b(2) HOUSE COMMITTEE ON PUBLIC WORKS

H.R. REP. No. 92-911, 92d Cong., 2d Sess. (1972)

FEDERAL WATER POLLUTION CONTROL ACT AMENDMENTS OF 1972

MARCH 11, 1972.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLATNIK, from the Committee on Public Works, submitted the following

REPORT

together with

ADDITIONAL AND SUPPLEMENTAL VIEWS

[To accompany H.R. 11896]

The Committee on Public Works, to whom was referred the bill (H.R. 11896) to amend the Federal Water Pollution Control Act, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

Strike out all after the enacting clause and insert in lieu thereof the following:

That this Act may be cited as the "Federal Water Pollution Control Act Amendments of 1972".

SEC. 2. The Federal Water Pollution Control Act is amended to read as follows:

"TITLE I—RESEARCH AND RELATED PROGRAMS

[p. 1]

"RESEARCH, INVESTIGATIONS, TRAINING, AND INFORMATION

"SEC. 104.

* * * * * *

"(l) (1) The Administrator shall, after consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, as soon as practicable but not later than October 3, 1972, develop and issue to the States for the purpose of carrying out this Act the latest scientific knowledge available in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

"(2) The President shall, in consultation with appropriate local, State, and Federal agencies, public and private organizations, and interested individuals, conduct studies and investigations of methods to control the release of pesticides into the environment which study shall include examination of the persistency of pesticides in the water environment and alternatives thereto. The President shall submit reports, from time to time, on such investigations to Congress together with his recommendations for any necessary legislation.

[p. 5]

ANALYSIS OF THE BILL

Section 2.—

Section 104.—Research, Investigations, Training and Information.

* * * * *

Subsections (d), (e), (g), (h), (i), (k), and (l) are basically extensions of the existing law with relatively minor changes.

In regard to these subsections the following items should be noted: (1) The rewriting of subsection (e) does not increase the number of authorized laboratories at any one area of the country, (2) the report relating to training required by subsection (g)(4) is meant to be a new report, and not in lieu of previously authorized reports, (3) the reference to cooperation with the Coast Guard in subsection (i) is to indicate that the Committee recognizes the extremely important role of that agency in this program, and expects that the Administrator will work closely with the Coast Guard in a manner which would preclude any differences as to which agency is the lead agency, (4) the Administrator is granted a 6-month extension on the requirements of subsection (l)(1) and the reports required by subsection (l)(2) are in addition to and not in lieu of the report required in the existing law.

[p. 81]

1.18b(3) COMMITTEE OF CONFERENCE

H.R. REP. 92–1465 92d Cong., 2d Sess. (1972)

[No Relevant Discussion on Pertinent Section]

1.18b(4) CONGRESSIONAL RECORD:

1.18b(4)(a) VOL. 117 (1971), Nov. 2: Considered and passed Senate

[No Relevant Discussion on Pertinent Section]

1.18b(4)(b) VOL. 118 (1972), Mar. 27–29; Considered and passed House, amended

[No Relevant Discussion on Pertinent Section]

1.18b(4)(c) VOL. 118 (1972), Oct. 4. House and Senate agreed to conference report

[No Relevant Discussion on Pertinent Section]

1.18b(4)(d) VOL. 118 (1972), Oct. 18. Senate and House overrode veto

[No Relevant Discussion on Pertinent Section]

1.19 INTEREST ON CERTAIN GOVERNMENT OBLIGATIONS, AS AMENDED

26 U.S.C. §103

(See "General 1.9a–1.9b" for legislative history)

§103. Interest on certain governmental obligations

(a) General rule.—Gross-income does not include interest on—

(1) the obligations of a State, a Territory, or a possession of the United States, or any political subdivision of any of the foregoing, or of the District of Columbia;

(2) the obligations of the United States; or

(3) the obligations of a corporation organized under Act of Congress, if such corporation is an instrumentality of the United States and if under the respective Acts authorizing the issue of the obligations the interest is wholly exempt from the taxes imposed by this subtitle.

(b) Exception.—Subsection (a) (2) shall not apply to interest on obligations of the United States issued after September 1, 1917 (other than postal savings certificates of deposit, to the extent they represent deposits made before March 1, 1941), unless under the respective Acts authorizing the issuance thereof such interest is wholly exempt from the taxes imposed by this subtitle.

(c) Industrial development bonds.—

(1) Subsection (a) (1) not to apply.—Except as otherwise provided in this subsection, any industrial development bond shall be treated as an obligation not described in subsection (a) (1).

(2) Industrial development bond.—For purposes of this subsection, the term "industrial development bond" means any obligation—

(A) which is issued as part of an issue all or a major portion of the proceeds of which are to be used directly or indirectly in any trade or business carried on by any person who is not an exempt person (within the meaning of paragraph (3)), and

(B) the payment of the principal or interest on which (under the terms of such obligation or any underlying arrangement) is, in whole or in major part—

(i) secured by any interest in property used or to be used in a trade or business or in payments in respect of such property, or

(ii) to be derived from payments in respect of property, or borrowed money, used or to be used in a trade or business.

(3) Exempt person.—For purposes of paragraph (2) (A), the term "exempt" person means—

(A) a governmental unit, or

(B) an organization described in section 501 (c) (3) and exempt from tax under section 501(a) (but only with respect to a trade or business carried on by such organization which is not an unrelated trade or business, determined by applying section 513(a) to such organization).

(4) Certain exempt activities.—Paragraph (1) shall not apply to any obligation which is issued as part of an issue substantially all of the proceeds of which are to be used to provide—

(A) residential real property for family units,

(B) sports facilities,

(C) convention or trade show facilities,

(D) airports, docks, wharves, mass commuting facilities for the local furnishing of electric energy or gas, directly related to any of the foregoing,

(E) sewage or solid waste disposal facilities or facilities for the local furnishing of electric energy or gas,

(F) air or water pollution control facilities, or

(G) facilities for the furnishing of water, if available on reasonable demand to members of the general public.

* * * * * * *

Aug. 16, 1954, c. 736, 68A Stat. 29; Dec. 10, 1971, Pub.L. 92–178, Title III, §315(a), 85 Stat. 529.

1.20 AMORTIZATION OF POLLUTION CONTROL FACILITIES, AS AMENDED

26 U.S.C. §169 (1969)

(See, "General 1.4a–1.4a(5)(c)" for legislative history)

§169. Amortization of pollution control facilities

(a) Allowance of deduction.—Every person, at his election, shall be entitled to a deduction with respect to the amortization of the amortizable basis of any certified pollution control facility (as defined in subsection (d), based on a period of 60 months. Such amortization deduction shall be an amount, with respect to each month of such period within the taxable year, equal to the amortizable basis of the pollution control facility at the end of such month divided by the number of months (including the month for which the deduction is computed) remaining in the period. Such amortizable basis at the end of the month shall be computed without regard to the amortization deduction for such month. The amortization deduction provided by this section with respect to any month shall be in lieu of the depreciation deduction with respect to such pollution control facility for such month provided by section 167. The 60-month period shall begin, as to any pollution control facility, at the election of the taxpayer, with the month following the month in which such facility was completed or acquired, or with the succeeding taxable year.

(b) Election of amortization—The election of the taxpayer to take the amortization deduction and to begin the 60-month period with the month following the month in which the facility is completed or acquired, or with the taxable year succeeding the taxable year in which such facility is completed or acquired, shall be made by filing with the Secretary or his delegate, in such manner, in such form, and within such time, as the Secretary or his delegate may by regulations prescribe, a statement of such election.

(c) Termination of amortization deduction.—A taxpayer which has elected under subsection (b) to take the amortization deduction provided in subsection (a) may, at any time after making such election, discontinue the amortization deduction with respect to the remainder of the amortization period, such discontinuance to begin as of the beginning of any month specified by the taxpayer in a notice in writing filed with the Secretary or his delegate before the beginning of such month. The depreciation deduction provided under section 167 shall be allowed, beginning with the first month as to which the amortization deduction does not apply, and the taxpayer shall not be entitled to any further amortization deduction under this section with respect to such pollution control facility.

(d) Definitions.—For purposes of this section—

(1) Certified pollution control facility.—The term "certified pollution control facility" means a new identifiable treatment facility which is used, in connection with a plant or other property in operation before January 1, 1969, to abate or control water or atmospheric pollution or contamination by removing, altering, disposing, or storing of pollutants, contaminants, wastes, or heat and which—

(A) the State certifying authority having jurisdiction with respect to such facility has certified to the Federal certifying authority as having been constructed, reconstructed, erected, or acquired in conformity with the State program or requirements for abatement or control of water or atmospheric pollution or contamination; and

(B) the Federal certifying authority has certified to the Secretary or his delegate (i) as being in compliance with the applicable regulations of Federal agencies and (ii) as being in furtherance of the general policy of the United States for cooperation with the States in the prevention and abatement of water pollution under the Federal Water Pollution Control Act, as amended (33 U.S.C. 466 et seq.), or in the prevention and abatement of atmospheric pollution and contamination under the Clean Air Act, as amended (42 U.S.C. 1857 et seq.).

(2) State certifying authority.—The term "State certifying authority" means, in the case of water pollution, the State water pollution control agency as defined in section 13 (a) of the Federal Water Pollution Control Act and, in the case of air pollution, the air pollution control agency as defined in section 302 (b) of the Clean Air Act. The term "State certifying authority" includes any interstate agency authorized to act in place of a certifying authority of the State.

(3) Federal certifying authority.—The term "Federal certifying authority" means, in the case of water pollution, the Secretary of the Interior and, in the case of air pollution, the Secretary of Health, Education, and Welfare.

(4) New identifiable treatment facility.—For purposes of paragraph (1), the term "new identifiable treatment facility" includes only tangible property (not including a building and its structural components, other than a building which is exclusively a treatment facility) which is of a character subject to the allowance for depreciation provided in section 167, which is identifiable as a treatment facility, and which—

(A) is property—

(i) the construction, reconstruction, or erection of which is completed by the taxpayer after December 31, 1968, or

(ii) acquired after December 31, 1968, if the original use of the property commences with the taxpayer and commences after such date, and

(B) is placed in service by the taxpayer before January 1, 1975.

In applying this section in the case of property described in clause (i) of subparagraph (A), there shall be taken into account only that portion of the basis which is properly attributable to construction, reconstruction, or erection after December 31, 1968.

(e) **Profitmaking abatement works, etc.**—The Federal certifying authority shall not certify any property under subsection (d) (1) (B) to the extent it appears that by reason of profits derived through the recovery of wastes or otherwise in the operation of such property, its costs will be recovered over its actual useful life.

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Aug. 16, 1954, c. 736, 68A Stat. 55, added Pub.L. 91-172, Title VII, § 704 (a), Dec. 30, 1969, 83 Stat. 667.

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2.1 E.O. 11643, ENVIRONMENTAL SAFEGUARDS ON ACTIVITIES FOR ANIMAL DAMAGE CONTROL ON FEDERAL LANDS

February 9, 1972, 37 Fed. Reg. 2875

EXECUTIVE ORDER 11643

Environmental Safeguards on Activities for Animal Damage Control on Federal Lands

By virtue of the authority vested in me as President of the United States and in furtherance of the purposes and policies of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and the Endangered Species Conservation Act of 1969 (16 U.S.C. 668aa), it is ordered as follows:

SECTION 1. *Policy.* It is the policy of the Federal Government to (1) restrict the use on Federal lands of chemical toxicants for the purpose of killing predatory mammals or birds; (2) restrict the use on such lands of chemical toxicants which cause any secondary poisoning effects for the purpose of killing other mammals, birds, or reptiles; and (3) restrict the use of both such types of toxicants in any Federal programs of mammal or bird damage control that may be authorized by law. All such mammal or bird damage control programs shall be conducted in a manner which contributes to the maintenance of environmental quality, and to the conservation and protection, to the greatest degree possible, of the Nation's wildlife resources, including predatory animals.

SEC. 2. *Definitions.* As used in this order the term:

(a) "Federal lands" means all real property owned by or leased to the Federal Government, excluding (1) lands administered by the Secretary of the Interior pursuant to his trust responsibilities for Indian affairs, and (2) real property located in metropolitan areas.

(b) "Agencies" means the departments, agencies, and establishments of the executive branch of the Federal Government.

(c) "Chemical toxicant" means any chemical substance which, when ingested, inhaled, or absorbed, or when applied to or injected into the body, in relatively small amounts, by its chemical action may cause significant bodily malfunction, injury, illness, or death, to animals or man.

(d) "Predatory mammal or bird" means any mammal or bird which habitually preys upon other animals or birds.

(e) "Secondary poisoning effect" means the result attributable to a chemical toxicant which, after being ingested, inhaled, or absorbed, or when applied to or injected into, a mammal, bird, or reptile, is retained in its tissue, or otherwise retained in such a manner and quantity that the tissue itself or retaining part if thereafter injested by man, mammal, bird, or reptile, produces the effects set forth in paragraph (c) of this section.

(f) "Field use" means use on lands not in, or immediately adjacent to, occupied buildings.

SEC. 3. *Restrictions on Use of Chemical Toxicants.*

(a) Heads of agencies shall take such action as is necessary to prevent any Federal lands under their jurisdiction, or in any Federal program of mammal or bird damage control under their jurisdiction:

(1) the field use of any chemical toxicant for the purpose of killing a predatory mammal or bird; or

(2) the field use of any chemical toxicant which causes any secondary poisoning effect for the purpose of killing mammals, birds, or reptiles.

(b) Notwithstanding the provisions of subsection (a) of this section, the head of any agency may authorize the emergency use on Federal lands under his jurisdiction of a chemical toxicant for the purpose of killing predatory mammals or birds, or of a chemical toxicant which causes a secondary poisoning effect for the purpose of killing other mammals, birds, or reptiles, but only if in each specific case he makes a written finding, following consultation with the Secretaries of the Interior, Agriculture, and Health, Education, and Welfare, and the Administrator of the Environmental Protection Agency, that any emergency exists that cannot be dealt with by means which do not involve use of chemical toxicants, and that such use is essential:

(1) to the protection of the health or safety of human life;

(2) to the preservation of one or more wildlife species threatened with extinction, or likely within the foreseeable future to become so threatened; or

(3) to the prevention of substantial irretrievable damage to nationally significant natural resources.

SEC. 4. *Rules for Implementation of Order.* Heads of agencies shall issue such rules or regulations as may be necessary and appropriate to carry out the provisions and policy of this order.

RICHARD NIXON.

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REGULATIONS

3.1 Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, U.S. Environmental Protection Agency, 40 C.F.R. §162.1–162.36 (1971).

3.2 Interpretations, Regulations for the Enforcement of FIFRA, U.S. Environmental Protection Agency, 40 C.F.R. §162.100–162.125 (1971).

3.3 Certification of Usefulness of Pesticide Chemicals, U.S. Environmental Protection Agency, 40 C.F.R. §163.1–163.12 (1971).

3.4 Rules Governing the Appointment, Compensation, and Proceedings of an Advisory Committee; and Rules of Practice Governing Hearings Under the Federal Insecticide, Fungicide, and Rodenticide Act, U.S. Environmental Protection Agency, 40 C.F.R. §164.1–164.44 (1972).

3.5 FAA Certification of Private Agricultural Operations, Federal Aviation Administration, 14 C.F.R. §137.1–137.77 (1968).

3.6 Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities, U.S. Environmental Protection Agency, 40 C.F.R. §180.1–180.1023 (1972).

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4.1 INTERDEPARTMENTAL AGREEMENTS

4.1a INTERDEPARTMENTAL AGREEMENT FOR PROTECTION OF PUBLIC HEALTH AND QUALITY OF ENVIRONMENT BETWEEN DEPARTMENTS OF AGRICULTURE, INTERIOR, AND HEALTH, EDUCATION, AND WELFARE CONCERNING ECONOMIC POISONS

March 3, 1970 35 Fed. Reg. 4014 (1970)

INTERDEPARTMENTAL AGREEMENT FOR PROTECTION OF PUBLIC HEALTH AND QUALITY OF ENVIRONMENT

Purpose. Coordination of the activities of the three Departments pertaining to economic poisons as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135), hereinafter referred to as pesticides, with reference to the review of current or proposed registrations to assure maximum protection of the public health, the well being of man, and the quality of the environment.

Existing departmental responsibilities. Each of the three Departments has certain statutory authority and responsibility relating to pesticides in the environment, as set forth below:

DEPARTMENT OF AGRICULTURE

1. Statutory authority under the Federal Insecticide, Fungicide, and Rodenticide Act for registration of pesticides.

2. Responsibility for research, education, information, regulatory, and action programs designed to protect the well being of man, crops, livestock, forests, ranges, habitats, products, structures, and premises against arthropod and other invertebrate pests, weeds, and fungi with equal concern for the protection of beneficial nontarget organisms and the quality of the environment.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

DHEW has the statutory authority and responsibility under the Federal Food, Drug, and Cosmetic Act for establishing safe tolerances for pesticides in or on raw agricultural commodities, processed food and potable water. The Department also has responsibilities for protecting the public from health, occupational, and environmental hazards related to the use and disposal of pesticides, and for other public health aspects such as the control of diseases and their vectors.

DEPARTMENT OF INTERIOR

USDI has statutory authority and responsibility under the Federal Water Pollution Control Act to carry out programs, to protect and enhance the quality of the Nation's waters including determining the effects of pesticides in water on health, welfare, and aquatic life. These responsibilities include establishing water quality standards for interstate waters. The Department also has statutory authority for the conservation of wild birds, fish, mammals, their food organisms and their environment as affected by pesticides and the appraisal of effects of pesticides on fish and wildlife.

Information. Each Department will keep each of the other Departments fully informed of developments in knowledge from research or other sources which may come into its possession in connection with matters referred to in this agreement. High priority shall be placed by each Department representative to respond to each of the other Departments' requests, whether written or oral, for any and all information concerning action pending or taken on pesticide matters.

Procedures—A. *General.* 1. Each Department will designate a qualified representative to act on behalf of such Department in carrying out the terms of this agreement. All communications from USDA, DHEW, and USDI will be directed to these representatives.

2. USDA shall furnish to the other Departments copies of each proposal received for registration or reregistration with the accompanying safety data (if any) and a request for an opinion from DHEW and USDI on the requested action in their areas of responsibility.

3. Within 15 working days, DHEW and USDI shall evaluate each registration or reregistration proposal in light of the data supplied and offer an opinion or provide a status report as to whether or not the registration should be granted or specify the additional data deemed necessary before such evaluation can be made. When either is unable to assess the public health or environmental risk without additional data, USDA shall advise the registrant of its inability to consider registration of the pesticide until the additional data requested have been received and reviewed by the respective Departments according to the following procedures described below.

B. *Specific.* 1. The Departmental Representative will accomplish review by his agency of each proposal and report results of such review to each of the other agencies within 15 working days of the receipt of the proposal. If there is insufficient information to reach a decision on the proposal, USDA will be contacted within such period of 15 working days and advised with particularity what additional information is needed for the necessary evaluation. Applicants for registration should not be discouraged from communicating with DHEW or USDI on registration matters of mutual interest, so long as the other representatives are informed of the details of such contact by memorandum thereof.

2. Upon receipt of such a request for further information, the USDA will make arrangements to obtain the additional information, if available, and furnish it to the Department making the request. USDA will withhold final action on the matter for 15 working days, from the date of furnishing the requested information or advice that such information is not available, pending receipt of the report of the other Department of the results of further review.

3. If a Department concludes that the registration should be rejected in whole or in part, this view shall be expressed in writing along with a statement of the reasons for the conclusion including the specific information, lack of information, or scientific judgment upon which these are based.

Upon being so notified, USDA will notify the party involved, i.e., the applicant or registrant, and offer him an opportunity to submit any data, views, or arguments with respect to the proposed rejection and any such submission shall be promptly referred to the other Department representatives who shall report to USDA the results of their review of the submission.

4. In the event that after the review of the additional data the Departments cannot agree on the approval of the proposal, any Department may request the formation of a Registration Review Panel for the purpose of making a complete review of the issues and related information or lack thereof and submit a detailed report of their findings. Each

Registration Review Panel shall be composed of two representatives from each of the three Departments with the chairman to be selected from the representatives of the Department from which the objections have come.

The Registration Review Panel shall prepare its report within 20 working days, including any minority opinions, and submit it to each of the three Departments.

5. The report(s) of the Registration Review Panel shall be reviewed by each Department within 15 working days of its receipt.

6. If significant differences between the Departments remain still unresolved, all data and information submitted by all parties shall be reviewed at the first monthly Interdepartment Pesticide Meeting after the reviews of the Registration Review Panel reports have been made.

7. In the event agreement is not reached among the Department representatives at the monthly Interdepartment Pesticide Meeting, a submission of the reports of the reviews referred to in paragraphs B–1 through B–6 above, will be referred at the request of the Secretary of the objecting Department to the Cabinet Committee on Environmental Quality. The referral shall be accompanied by a statement prepared by each Department analyzing the issues involved and setting forth the decision it recommends. The Cabinet Committee on Environmental Quality will consider such recommendations and make a written report, either accepting, rejecting, or modifying them.

8. Based upon consideration of the action of the Cabinet Committee, the Secretary of Agriculture will make the decision as to the specific action to be taken with respect to the matter on which the Department representatives were not in agreement, and will thereupon notify the other two Secretaries in writing in advance of the publication of the final determination if he has not followed the recommendations made by the objecting Department(s), specifically stating his reasons for such action.

9. When registration is granted, USDA shall supply to DHEW and USDI final printed labeling at the time of registration with a copy of the final letter to the registrant.

10. The Departmental representatives may review existing patterns of usage and registrations for particular pesticides. A conclusion by USDA, DHEW, or USDI that an existing pesticide use or registration may be detrimental to the public health or to the quality of the environment shall be transmitted to the other two Departments together with the supporting reasoning and information, with a recommendation for corrective action. Written information from all sources on the health or environmental aspects of such pesticides shall be submitted to a Registration Review Panel for review and recommendations. If USDA, DHEW, or USDI disagrees with the recommendations of the Registration Review Panel, that Department can initiate further review by the procedural steps described in paragraphs B–6 through B–8 above.

Interdepartment pesticide meetings and conferences. The Department representatives will meet jointly at an Interdepartment Pesticide Meeting once a month to provide a continuous dialogue concerning all aspects of their current activities and to promote cooperation and understanding among the Departments. Monthly reports concerning their activities will be made to the Secretaries of the three Departments, according to a mutually agreed upon format.

The Departmental representatives will arrange a general conference at least once each year to discuss research needs, research program and policy, and the application of research findings in action programs, including public information relating to pesticides. The Interdepartment Pesticide Conference will consider broad questions on policies relating to pesticides involving the interrelationships of control programs, research, registration, tolerances, the public health, and general departmental recommendations to the public.

In order to promote free interchange or information among the Departments involved under this agreement, each Department representative should be invited and encouraged to participate in conferences, meetings, and various symposiums with Federal, State, university, or industry people on possible matters of mutual interest.

Effective date and supersedure. This agreement shall become effective upon signature by the Secretaries of USDA, USDI, and DHEW, and shall supersede the agreement entitled "Interdepartmental Coordination of Activities Relating to Pesticides by the Department of Agriculture, the Department of Health, Education, and Welfare, and the Department of the Interior", published in the FEDERAL REGISTER on May 1, 1964 (29 F.R. 5808).

Dated: January 28, 1970.

CLIFFORD M. HARDIN,
Secretary of Agriculture.

ROBERT H. FINCH,
Secretary of Health,
Education, and Welfare.

WALTER J. HICKEL,
Secretary of the Interior.

4.1b AGREEMENT BETWEEN DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE AND ENVIRONMENTAL PROTECTION AGENCY

December 22, 1971, 36 Fed. Reg. 24234

AGREEMENT BETWEEN DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE AND ENVIRONMENTAL PROTECTION AGENCY

Notice Regarding Matters of Mutual Responsibility

The Department of Health, Education, and Welfare and the Environmental Protection Agency have drawn up an agreement regarding matters of mutual responsibility under the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act. It reads as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM OF AGREEMENT REGARDING MATTERS OF MUTUAL RESPONSIBILITY UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT AND FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

Reorganization Plan No. 3 of 1970 published in the FEDERAL REGISTER of October 6, 1970, stated in section 2, paragraph (4) that the functions vested in the Secretary of Health, Education, and Welfare of establishing tolerances for pesticide chemicals under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 346, 346a, and 348, were transferred to the Administrator of the Environmental Protection Agency effective December 2, 1970. After considering all of the various pesticide uses which have been subject to petition procedures under these three sections, and certain other economic poison uses subject both to the Federal Insecticide, Fungicide, and Rodenticide Act, 731 U.S.C. 35, and to the Federal Food, Drug, and Cosmetic Act, the Administrator of the Environmental Protection Agency and the Secretary of Health, Education, and Welfare have concluded that this agreement is needed to provide for the coordination of activities pertaining to economic poisons and to inform all concerned as to which agency will process the pesticide petitions for each type of use.

Reorganization Plan No. 3 also transferred to the Administrator of the Environmental Protection Agency the functions of the Secretary of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act. There are certain products which are subject to the requirements of both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the past, confusion, misunderstanding and inconvenience have resulted from procedures followed in connection with the proposed marketing of such products. The Administrator of the Environmental Protection Agency (EPA) and the Secretary of Health, Education, and Welfare are agreed that a new procedure should be followed, whereby the manufacturer would be informed (1) of the agency exercising primary jurisdiction regarding his product, (2) that the matter will be referred to the other agency for decision under the law of that agency, and (3) that approval for marketing the product will not be granted unless or until each agency has approved the marketing under its respective authority. This matter was the subject of a proposed statement of general policy and interpretation published in the FEDERAL REGISTER on August 5, 1970.

There are other procedures which should be established in order to facilitate the handling of matters which are of direct concern to both agencies. These matters involve issuance of regulations under section 406 of the FFDCA establishment of reference standards, exchange of information on certain programs, agreements with States and foreign countries on surveillance and enforcement activities on pesticide residues in food and publication of the Pesticide Analytical Manual.

The term "pesticide chemical" is defined in section 201(q) of the Federal Food, Drug, and Cosmetic Act as a substance which is an "economic poison" under the Federal Insecticide, Fungicide, and Rodenticide Act and which is used in the production, storage, or transportation of raw agricultural commodities. Economic poisons used on food crops before or after harvest and on food animals are included in this category. Economic poisons used on or concentrating in processed foods are treated in the Federal Food, Drug, and Cosmetic Act as food additives rather than pesticide chemicals.

Both agencies agree that:

1. The following petitions will be processed by the Environmental Protection Agency:

a. Petitions requesting tolerances or exemption from tolerances for residues of pesticide chemicals on raw agricultural commodities.

b. Petitions for food additive regulations required for residues of pesticide chemicals carrying over and concentrating in processed foods manufactured from treated raw agricultural commodities.

c. Petitions for regulations for residues of economic poisons from direct treatment of processed foods with fumigants or insecticides.

d. Petitions for food additive regulations to permit the safe use of economic poisons to impregnate food-packaging materials such as wrappers or bags to protect raw agricultural commodities from any pest or to protect processed foods from insects.

2. The following petitions will be processed by FDA:

a. Petitions for food additive regulations to permit use of sanitizers on food-contact surfaces.

b. Petitions for food additive regulations to permit the safe use of economic poisons and preservatives in processed food.

c. Petitions for food additive regulations to permit the safe use of economic poisons in food packaging material when such use is not covered by 1.d.

3. Applications for approval of drugs under FFDCA and for registration of economic poisons under FIFRA will be processed as follows:

a. Whenever a product is submitted to either FDA or EPA for approval and it is believed by either agency that the product is subject to the requirements of both the FFDCA and the FIFRA, an interagency determination will be made and an agreement reached with respect to (1) whether the product is subject to the requirements of the FFDCA and FIFRA, (2) whether particular claims are "economic poison" or "drug" claims and (3) whether the representations made for the product, including the implications to be drawn therefrom, are primarily "economic poison" or "drug" representations.

b. Whenever application is made to EPA for registration of a product that is both a drug and an economic poison and determination has been made that the principal claims or representations relate to an economic poison, EPA will withhold registration of the product under FIFRA until it has been informed by FDA that the product complies with the provisions of the laws administered by FDA.

c. Whenever application is made to FDA for approval of a product that is both a drug and an economic poison and determination has been made that the principal claims or representations relate to a drug, FDA will not approve a new drug application, a new animal drug application, or an antibiotic application without first being advised by EPA that the claims or representations subject to the provisions of the FIFRA are warranted and that the product is eligible for registration under that act.

d. Whenever application is made to EPA for the registration of a product that is both a drug and an economic poison and determination has been made that the principal claims or representations relate to a drug, the matter will be referred by EPA to FDA and the matter will thereafter be handled as if the application had been originally made to FDA.

e. Whenever application is made to FDA for approval of a product that is both an economic poison and a drug and determination has been made that the principal claims or representations relate to an economic poison, the matter will be referred by FDA to EPA and the matter will thereafter be handled as if the application had been originally made to EPA.

f. Neither agency will approve the marketing of a product under the law administered by it if the product would not be in full compliance with the requirements of a law administered by the other.

4. If the poisonous or deleterious substance referred to in section 406 of the Federal Food, Drug, and Cosmetic Act is present in food primarily as a result of its use as a pesticide chemical, or an economic poison, any regulation establishing a tolerance for such substance in food will be promulgated by the Environmental Protection Agency. Any other regulations under section 406 will be promulgated by FDA.

5. EPA will have primary responsibility for maintenance of an analytical reference standards repository of pesticides for which tolerances are established. FDA will transfer to EPA those samples which have been prepared for this purpose. Upon request, portions of these samples will be made available to the FDA and local enforcement authorities as needed for use in official analysis.

6. Each agency will appoint an individual and alternates who shall be responsible for interagency cooperation and coordination.

a. These representatives, with staff support as desired, shall meet regularly on a mutually agreeable schedule to discuss program and policy coordination and to establish operating procedures between the agencies. Primary functions of the representatives are: (i) To assure adherence to the general provsiions of paragraphs 1–4 above, inclusive; (ii) to promote mutual concurrence on chemical, toxicologic, and pharmacologic requirements for pesticide tolerances; (iii) to provide for complete and timely exchange of information concerning proposed tolerances, administrative guidelines, methodology, research programs, monitoring, surveillance and enforcement programs, and legal action; (iv) to provide that FDA will continue responsibility for agreements with States and foreign countries on surveillance and enforcement activities on pesticide residues in food; (v) to provide that where the official U.S. delegate to international organizations is either EPA or FDA this will not automatically preclude representation by the other agency; and (vi) to provide that publication of FDA's Pesticide Analytical Manual for residues in foods and other environmental substrates will be continued as a joint FDA–EPA sponsorship under editorial management consisting of representatives of both agencies.

b. Issues arising out of the above provisions which are not resolved after two regularly scheduled meetings shall be submitted through the organizational structure of each agency for resolution.

c. Agency representatives may propose additional agreements concerning these and other matters affecting interagency coordination and cooperation on the health aspects of pesticides and their residues in food and drugs. These proposals may be jointly approved by the Deputy Assistant Administrator for Pesticides Programs EPA, and the Commissioner of Food and Drugs, HEW.

For the Department of Health, Education, and Welfare.

J. G. VENEMAN,
Acting Secretary.

JUNE 17, 1971.

CHARLES C. EDWARDS,
Commissioner.

MAY 11, 1971.

For the Environmental Protection Agency.

WILLIAM D. RUCKELSHAUS,
Administrator.

SEPTEMBER 4, 1971.

Effective date. This agreement became effective on November 10, 1971.

Dated: December 9, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

4.1c INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE AND THE ENVIRONMENTAL PROTECTION AGENCY FOR JOINT PARTICIPATION IN THE NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH, APRIL 1, 1971

INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE AND THE ENVIRONMENTAL PROTECTION AGENCY FOR JOINT PARTICIPATION IN THE NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PINE BLUFF, ARKANSAS

Purpose and General Policy:

On January 27, 1971, President Nixon announced the establishment of a National Center for Toxicological Research at Pine Bluff, Arkansas. The Food and Drug Administration will administer the facility in a manner that is responsive to the needs of the signatory agencies when programs require research and development suitable to the Center. In addition, other Federal agencies, universities, and industry groups will be invited to participate to the extent that their participation appears feasible and desirable. Priority is to be given to those programs of concern to the participating agencies, particularly if these programs are jointly planned or supported. An effort will be made to maintain maximum flexibility in the operation and management of the facility to ensure responsiveness to the changing needs of participating agencies.

Principles of Operation:

There will be a Director of the Center with overall authority to operate and manage the Center in accordance with policies and priorities established by a policy board. The Director will be appointed by the Commissioner of the Food and Drug Administration after consultation with and approval by the policy board.

The policy board will consist of government employees appointed by the Secretary of Health, Education, and Welfare, and the Administrator of the Environmental Protection Agency, with provision for additional members as needed.

All members of the board must have an opportunity to express their opinions and vote on all major decisions.

The Director will be authorized to arrange for operations of all or any portion of the Center by contract with a suitable organization, if after consultation with the policy board, such contract operations seem desirable.

Fiscal and agency audit functions will be the responsibility of the Food and Drug Administration.

Functions of Director:

* * * * * * *

The Director shall provide a full-time staff of one or more people acceptable to the policy board to serve as Secretariat to the policy board. The Director will provide managerial supervision and facilities to this staff, but will not interfere in any way with any instructions the Secretariat staff receives from the board. He will assure that such staff as well as the members of the board have full access, with his knowledge, to all activities of the Center.

Functions of Policy Board:

The policy board will meet at regular intervals, no less than six times per year primarily at the Center, to consider and develop policies, scientific priorities, and related program budgets and such other matters as may affect the scientific excellence of the Center and to assure its flexibility to serve the purposes for which it is established. An interim board is hereby established to serve not beyond September 30, 1971, by which time the permanent policy board will be designated. The membership of the interim board will consist of three voting members appointed by the Secretary of Health, Education, and Welfare, three voting members appointed by the Administrator of the Environmental Protection Agency, one observer from the Office of Science and Technology, and one observer from the Council on Environmental Quality. The six voting members shall elect a chairman from among themselves.

The interim board will proceed immediately to develop a charter and operating procedures to be approved by the Secretary (HEW) and the Administrator (EPA). The charter and operating procedures will specify: the structure and membership of the board, the procedure for appointing members (which procedure shall in any event provide for representation in equal numbers from HEW and EPA), a mechanism for participation of other organizations that should participate in the policy and priority setting, a mechanism for obtaining scientific advice from consultants, the selection of the chairman, the frequency of meetings, the definition of a quorum, the procedures for convening special meetings, and a method of amending the charter and operating procedures.

Matters upon which the policy board will provide advice or guidelines to the Director include:

1. Organization of the Center
2. Qualifications and selection of key personnel
3. Overall budget requests and modifications
4. General plans and overall protocols of major projects.
5. Major building construction and modification requirements
6. Arrangements for contracts for major activities of the Center
7. Contingencies which require experimentation and expenditures of contingency funds
8. Such other matters as the Director or members of the board considers appropriate

Protection of the scientific integrity of the laboratory is paramount. To this end, it should be understood that no regulatory body will be obligated in any way to give any special weight to results of activities of the Center or interpretation of those results; by the same token, the board rather than individual scientists, will be the source of any official interpretations of Center activities desired by regulatory agencies.

As soon as possible, the interim board will recommend contracts or other activities to the Commissioner of FDA that will facilitate and expedite the establishment of appropriate activities of the Center, making use of the funds being held in reserve for this purpose.

Functions Reserved to the Commissioner of FDA:

1. Appointment of the Director of the Center after consultation with an approval by the policy board
2. Establishment of procedures to assure the legal and fiscal responsibilities of the Center

Effective Date:

This plan of operation will become effective on the first day after it has been signed by both the Secretary of HEW and the Administrator of EPA.

Date: Apr. 1, 1971

/s/ ELLIOT L. RICHARDSON
Secretary, Health, Education and Welfare

Date: Apr. 1, 1971

/s/ WILLIAM D. RUCKELSHAUS
Administrator, Environmental Protection Agency

4.1d MEMORANDUM OF AGREEMENT BETWEEN THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND THE UNITED STATES DEPARTMENT OF AGRICULTURE, JUNE 14, 1972

MEMORANDUM OF AGREEMENT BETWEEN THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND THE UNITED STATES DEPARTMENT OF AGRICULTURE

I. Purpose

The purpose of this agreement is to establish policies and procedures that will provide for a continuing working relationship between the Environmental Protection Agency (EPA) and the Extension Service (ES), United States Department of Agriculture (USDA) in support of programs which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; and to enrich the understanding of the ecological system and natural resources important to the Nation.

II. Background

The National Environmental Policy Act of 1969 directs all Federal agencies to utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and decision making which may have an impact on man's environment. Further, the Intergovernmental Cooperation Act of 1968 specifies that Federal agencies administering development assistance programs will consult with other affected agencies in an effort to assure fully coordinated programs.

The Extension Service carries out educational programs related to environmental concerns in the area of agricultural production and marketing, natural resources development and management, horticulture, disaster prevention and relief, and associated pollution abatement practices.

The Environmental Protection Agency has responsibility for establishing environmental standards, monitoring and enforcing standards, conducting research and development, and providing training and technical assistance which are designed to improve the quality of the environment. These involve programs dealing with water quality, air quality, soil pollutants, radiation contamination, pesticide use, solid waste and the introduction and use of chemicals affecting human and animal health.

III. Under terms of this agreement, the Extension Service, USDA, will:

a. Assign appropriate staff to function in a liaison capacity with the EPA staff in areas where mutuality of interest exists and cooperative programs are developed.

b. Collaborate with EPA to provide through State cooperative extension services information and education to farmers, agricultural service firms and others concerning safe and effective methods of application, use and storage, and disposal of excess pesticides and pesticide containers.

c. Develop and conduct education programs through and in cooperation with the State cooperative extension services on waste management stemming from agricultural practices, including animal, crop processing, and forest wastes, in accordance with EPA and/or State environmental water quality standards and guidelines.

d. Develop and conduct training programs through State cooperative extension services and in collaboration with EPA, as appropriate, on pesticides and other environmental improvements relating to air, water, and soil pollution in addition to b and c above. Keep EPA informed about training programs in these areas conducted by State cooperative extension services.

e. Provide EPA with current information on environmental problems concerning agriculture (including marketing and processing) and rural communities and information from State cooperative extension services to assist EPA in evaluating current and potentially new programs in areas of mutual concern.

f. Assist in negotiations of contracts and agreements, as appropriate, between the State cooperative extension services and EPA.

g. Encourage communication and cooperation between State cooperative extension services and the appropriate EPA Regional Office personnel, including the assignment of personnel to serve in a liaison capacity.

h. Provide EPA with copies of all USDA publications and releases dealing with pesticides and the environment, pesticide use, and pesticide wastes immediately after publication.

IV. Under terms of this agreement, the Environmental Protection Agency will:

a. Assign staff members to serve in liaison capacity with the USDA in areas where mutuality of interest exists and cooperative programs are developed.

b. Transmit information on changes in pesticide regulations and registrations directly to designated leaders in State extension services and to the ES/USDA.

c. Coordinate with ES/USDA in the design, development, and support of training programs and pilot or demonstration projects conducted on a regional or State level by participating cooperative services.

d. Encourage communication and cooperation between EPA Regional Office pesticide generalists and the appropriate State cooperative extension services, including the assignment of appropriate staff to work with State extension personnel.

e. Work closely with the ES/USDA and State cooperative extension services as well as other State agencies in the development of training programs for pesticide applicators, including the utilization of State training facilities and capabilities. Furnish the Extension Service with copies of training and public information materials on pesticides and the environment.

f. Provide ES/USDA with copies of all EPA publications and releases dealing with pesticides and the environment, pesticide use, and pesticide wastes immediately after publication.

V. **This memorandum shall be implemented as follows:**

a. The Environmental Protection Agency and the Department of Agriculture each will assign a senior staff officer who will serve in a liasion capacity.

b. Any joint endeavors involving reimbursement or transfers of funds between the two parties will be handled in accordance with the Economy Act and normal Government financial procedures.

Date: June 14, 1972

DAVID I. DOMINIC
Assistant Administrator for Categorical Programs
U.S. ENVIRONMENTAL PROTECTION AGENCY

Date: June 14, 1972

J. PHIL CAMPBELL
Under Secretary of Agriculture
U.S. DEPARTMENT OF AGRICULTURE

4.1e INTERAGENCY AGREEMENT BETWEEN THE U. S. DEPARTMENT OF AGRICULTURE AND THE U. S. ENVIRONMENTAL PROTECTION AGENCY, Jan. 23, 1973.

I. Purpose

The June 1972 decision of the Administrator, Environmental Protection Agency (EPA), to ban the use of DDT has required that growers look to alternative pesticides whose use may involve a variety of hazards. This in turn requires that the users of these materials receive special training in their safe use beyond that now being provided in on-going State Extension Services programs. EPA has agreed to share the cost of the needed additional training with the Extension Services of selected States. The June 14 Memorandum of Understanding between EPA and the Extension Service (ES), U. S. Department of Agriculture provides for collaboration in the conduct of training activities relating to the safe use of pesticides including those involving the State Extension Services. The purpose of this agreement is to specify the conditions under which EPA will utilize the existing administrative arrangements between ES and specified State Extension Services as a means of carrying out these jointly funded training activities.

II. Scope of Work

The work to be performed by the ES will include the following:

1. Reviewing patterns of pesticides usage in all 50 States so as to determine those states in which additional training is required in the safe use of replacement pesticides. This phase of the work has been completed and has resulted in the identification of Virginia, South Carolina, North Carolina, Georgia, Florida, Tennessee, Kentucky, Alabama, Mississippi, Arkansas, Texas, Louisiana, Oklahoma, and Missouri as requiring training programs beyond those now provided by on-going efforts of the Extension Services of those states.
2. Obtaining proposals from the Extension Services of each of the states listed above which outlines a plan for providing the additional training needed by that state. While these plans may vary according to the specific problems and capabilities of the individual states, they should include
   (1) Numerical description of the problem; i.e., number of individuals who might be poisoned absent a new federally funded program.
   (2) Brief description of expected problems in implementing proposed program.
   (3) A detailed plan of events schedule.
   (4) Proposed method of regular monthly activity reporting and evaluation of effectiveness.
3. Participating with EPA representatives in the review of proposed State plans to determine if the plans represent a satisfactory basis for the conduct of a jointly funded training program.
4. Utilizing existing ES administrative arrangements with State Extension Services as a means for entering into

contracts with the above states for the conduct of training programs based upon State proposals.

5. Providing technical and administrative direction of the work performed under each of these contracts.
6. Participating with EPA in evaluating the effectiveness of the training activities in each State.

III. Provisions

The following special provisions are applicable to the performance of work under this agreement:

1. Contractual arrangements with the State Extension Services will provide for a sharing of cost in ratio of 750/1100 Federal funds to 350/1100 State funds.
2. The total funds to be transferred from EPA to USDA in support of this joint program are $750,000. The transfer of funds from the USDA to the individual State Extension Services will be on a 40–40–20 basis; i.e., 40 percent as the State plan is approved, an additional percent will be released midway through the project (April 1, 1973), and the final 20 percent prior to the completion of the program (June 1, 1973); the second and third allocations will be made subsequent to on-going review and final approval of the individual continuing State programs by EPA Regional Project Managers.
3. Each proposed State plan must have the written approval of both the EPA and ES Project Officers before it is used as a basis for entering into a contract.
4. EPA Regional Office staffs will participate directly with the State Extension Services in the development of mutually acceptable proposed State plans. Regional Office staffs will carry out close liaison with the individual State Extension Services so as to coordinate the work accomplished under these contracts with direct EPA efforts in the area of pesticide safety.
5. Contracts with individual State Extension Services will include requirements for the submission of the reports listed in Section IV directly to EPA and ES Project Officers.

IV. Duration of Agreement

This agreement will cover the period through June 1, 1973, or until completion of the work whichever occurs first.

V. Reports

A monthly report will be submitted by each State Extension Service to the EPA Regional Project Managers which will:

1. Compare actual expenditures by line item with those projected in the approved State plan.
2. Indicate the number of safety aides hired and the number of safety aides receiving training.
3. A description of the actual training provided to members of the target audience specifying the type of training and the number of persons receiving training.
4. The results of statistically valid sample audits of training activity as agreed upon by EPA and USDA/ES.

VI. Project Officers

Mr. Paul Pendorf, Room 1037, 401 M St., S.W., Washington, D. C. (202–755–0320) will serve as Project Officer for EPA; Dr. L. C. Gibbs, Room 5513, South Agriculture Building, 14th and Independence Ave., S.W., Washington, D. C. (202–447–4481) will serve as Project Officer for ES.

VII. Funding

EPA will transfer $750,000 to ES to cover EPA's share of the costs under the contracts entered into by ES pursuant to this agreement. This amount is to be allocated to individual State Extension Services in accordance with the provisions of clause III(2) above and the State by State distribution of funds as set forth in Attachment A. Any of this foregoing amount remaining unexpended after the completion of the work under these contracts shall be returned to EPA.

Upon execution of this agreement an allocation transfer will be made from EPA to the ES, by Standard Form 1151, "Non-Expenditure Transfer Authorization." Funds will be withdrawn from Office of Pesticides Program Sub-Element No. PE 2E5367–32 for this purpose.

VIII. Termination and Amendment

In case the ban on the use of DDT is lifted by court action, the program may be stopped at a mutually agreed date and unused funds returned. The program may be extended indefinitely if mutually agreed to.

IX. Authority

This agreement is entered into pursuant to Section 23(c) of Federal Environmental Pesticides Control Act of 1972, PL 92-516.

Date Jan. 23, 1973

DAVID D. DOMINICK
Assistant Administrator for Categorical Programs
U. S. ENVIRONMENTAL PROTECTION AGENCY

Date Feb. 3, 1973

/s/ J. PHIL CAMPBELL
Under Secretary of Agriculture
U.S. DEPARTMENT OF AGRICULTURE

ATTACHMENT A

State	Funding
Alabama	$ 86,500
Arkansas	38,475
Florida	13,650
Georgia	63,400
Kentucky	3,825
Louisiana	25,425
Mississippi	82,050
Missouri	37,050
North Carolina	173,100
Oklahoma	27,825
South Carolina	56,025
Tennessee	86,500
Texas	36,150
Virginia	20,025
	$750,000

4.2 SELECTED REPORTS

4.2a THE PRESIDENT'S SCIENCE ADVISORY COMMITTEE REPORT ON PESTICIDES, MAY 14, 1963

I. INTRODUCTION

Man's primary concerns have always been the struggle for survival and improvement of his lot. As his numbers increased, he attained greater ability to manipulate his environment. In the process he sometimes inflicted damage on himself and on his surroundings. Advances have always entailed a degree of risk which society must weigh and either accept, or reject, as the price of material progress.

A major step in civilization was the domestication of food plants. With the birth of organized agriculture and the resultant concentration of crops and animals, the stage was set for outbreaks of pests. Until that time man had to search for food as did the pests. Afterwards neither had to search; instead pest control became necessary. The welfare of an increasing human population requires intensified agriculture. This in turn enables the pests to increase, which necessitates the use of pesticides with their concomitant hazards. It thus seems inevitable that, as the population increases, so do certain hazards.

In an effort to understand and evaluate these problems, the Panel undertook a review of the information relevant to pesticides, including experimental data and the various administrative procedures which are designed for the protection of the public. The Panel could not have accomplished this review without the assistance it received from the Departments of Agriculture, Interior, Defense, and Health, Education and Welfare, as well as from many individuals throughout the country.

The information provided to the Panel has demonstrated how remarkably effective the modern organic chemicals are in facilitating both the control of insect vectors of disease and the unprecedented production of food, feed and fiber. The use of pesticides associated with the production of our food is carefully controlled by the growers and supervised by agricultural specialists and the Food and Drug Administration. As a result, the residue levels measured on foods intended for interstate and foreign commerce are low and rarely above federal tolerance limits.

The Panel believes that the use of pesticides must be continued if we are to maintain the advantages now resulting from the work of informed food producers and those responsible for control of disease. On the other hand, it has now become clear that the proper usage is not simple and that, while they destroy harmful insects and plants, pesticides may also be toxic to beneficial plants and animals, including man. Their toxic effects in large doses are well known and precautions can be taken to see that humans are never needlessly exposed. But we must now also take measures to ensure that continued exposures to small amounts of these chemicals in our environment will not be harmful over long periods of time.

Review of pesticides brings into focus their great merits while suggesting that there are apparent risks. This is the nature of the dilemma that confronts the nation. The Panel has attempted to state the case—the benefits, the hazards and the methods of controlling the hazards. It can suggest ways of avoiding or lessening the hazards, but in the end society must decide, and to do so it must obtain adequate information on which to base its judgments.

The decision is an uncomfortable one which can never be final but must be constantly in flux as circumstances change and knowledge increases.

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II. GAINS FROM THE USE OF PESTICIDES

Our material standard of living has been greatly elevated during the twentieth century by increased control over the environment. Few recent developments have been so effective or have had application in such a wide range of human endeavor as the pesticide chemicals. Although pesticides have been used for centuries as adjuncts in pest control, the great advances of the last 20 years resulting from the discovery, manufacture and application of new compounds have changed their role in many instances to that of the principal and frequently sole control measure.

Pesticides have made a great impact by facilitating the production and protection of food, feed and fibre in greater quantity and quality; by improving health; and by keeping in check many kinds of nuisance insects and unwanted plants. Agricultural needs have entailed the largest applications of pesticides in this country. Productivity has been so increased that famine is an unknown experience to the people of the developed nations. Mechanization, improved fertilizers, and the breeding of productive and disease-resistant crops have also contributed importantly. In addition, pesticides have made possible the economical production of many crops which otherwise would be available only to a limited number of wealthy consumers.

While reducing food losses, pest control has also resulted in foodstuffs of the highest quality. Today, for example, sweet corn, potatoes, cabbage, apples and tomatoes are all available unmarred, and the American housewife is accustomed to blemish-free products. Citrus fruits are seldom damaged or lost because of scale insects, fruit flies or diseases, and the cost of animal protein is lower because large losses of cattle from tick fever and grubs no longer occur.

Modern agricultural efficiency is maintained not only through the use of insecticides, but also by means of herbicides, fungicides, rodenticides, nematocides, plant growth regulators and other chemicals. Their benefits extend beyond crops raised for direct human consumption. They permit efficient production of forage and grains, which in turn are needed for a productive livestock economy. In addition, they allow profitable yields of non-food crops such as cotton, tobacco and timber. Pesticides have not, however, reached an optimum of effectiveness. More than 100 established pests have developed resistance to one or more previously effective chemicals, and new pests are occasionally introduced by international traffic.

Rapid population growth and concomitant decrease in land available for agriculture necessitate greater crop yields per acre and reduction of losses and spoilage in stored foods. Moreover, many products must be protected during the process of manufacture and distribution.

Besides enabling spectacular increases in agricultural production, pesticides have freed man from communicable diseases to an unprecedented extent. In less developed areas of the world, malaria, typhus and yellow fever, previously controlled only with great difficulty, are now limited and in some locations eradicated. In each case, pesticides have facilitated control of the insect vector. At some stage of their natural history a number of the major communicable diseases involve an intermediate host or vector. Most successful [p. 2] disease control programs have been directed at eliminating this link in the chain of transmission, rather than treating man after he has contracted the disease.

However, control programs have not achieved disease eradication. Malaria is still the disease responsible for the largest number of deaths in the world each year, although new cases are rare in the United States. Yellow fever, schistosomiasis, plague and some rickettsial diseases are almost unknown in the mainland of North America, but they still take a large toll of human lives in the rest of the world. Furthermore, reservoirs of disease in animals, and insects which can transmit them, will remain with us for the predictable future both in this country and in other parts of the world thus requiring a continued effort to control them.

An additional complication in disease control is that the insect vectors, such as mosquitoes that transmit malaria, may produce resistant populations capable of transmitting the resistance to pesticides from generation to generation. In order to keep up with the successive threats of insect vectors as they develop resistance to one chemical after another, it is important to enlarge and improve our capability for controlling pests.

Pesticides also have made control of many nuisance insects and plants financially feasible. Were the costs higher, the funds for their control would be used by other more critical demands on the economy. For example, it might be too expensive to control the varieties of mosquitoes that breed in marshes and estuaries which do not transmit disease, but limit man's enjoyment of some of the most desirable recreational areas. Similarly, elimination of roaches from kitchens, aphids from roses and fungi from golf greens are very desirable but nonessential benefits.

Efficient agricultural production, protection of health and elimination of nuisances are now required and expected by modern man. The methods used to accomplish these ends must continue to improve, although their present scope and magnitude far exceed the few examples included here. It is certain that coming years will witness sophistication of methods and new uses for which pesticides were not originally conceived.

III. THE HAZARDS OF USING PESTICIDES

Evidence of increasing environmental contamination by pesticide chemicals has generated concern which is no longer limited to citizens of affected areas or members of special interest groups. During two decades of intensive technical and industrial advancement we have dispersed a huge volume of synthetic compounds, both intentionally and inadvertently. Many, such as detergents, industrial wastes and pesticides are now found far from the point of initial dispersal.

Today, pesticides are detectable in many food items, in some clothing, in man and animals, and in various parts of our natural surroundings. Carried from one locality to another by air currents, water runoff, or living organisms (either directly or indirectly through extended food chains), pesticides have travelled great distances and some of them have persisted for long periods of

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time. Although they remain in small quantities, their variety, toxicity and persistence are affecting biological systems in nature and may eventually affect human health. The benefits of these substances are apparent. We are now beginning to evaluate some of their less obvious effects and potential risks.

Precisely because pesticide chemicals are designed to kill or metabolically upset some living target organism, they are potentially dangerous to other living organisms. Most of them are highly toxic in concentrated amounts, and in unfortunate instances they have caused illness and death of people and wildlife. Although acute human poisoning is a measurable and, in some cases, a significant hazard, it is relatively easy to identify and control by comparison with potential, low-level chronic toxicity which has been observed in experimental animals.

The Panel is convinced that we must understand more completely the properties of these chemicals and determine their long-term impact on biological systems including man. The Panel's recommendations are directed toward these needs, and toward more judicious use of pesticides or alternate methods of pest control, in an effort to minimize risks and maximize gains. They are offered with the full recognition that pesticides constitute only one facet of the general problem of environmental pollution, but with the conviction that the hazards resulting from their use dictate rapid strengthening of interim measures until such time as we have realized a comprehensive program for controlling environmental pollution.

A. CLASSES OF COMPOUNDS

The term pesticide broadly includes compounds intended for a variety of purposes. They are used to control insects, mites, ticks, fungi, nematodes, rodents, pest birds, predatory animals, rough fish, plant diseases and weeds; and also to act as regulators of plant growth, as defoliants, and as desiccants. As of June, 1962, almost 500 compounds incorporated in more than 54,000 formulations were registered for use in the United States.

1. The chlorinated hydrocarbons containing carbon, hydrogen, and chlorine are the pesticides used in greatest tonnage. The most familiar are DDT, dieldrin, aldrin, endrin, toxaphene, lindane, methoxychlor, chlordane, and heptachlor. Among those used extensively as herbicides are 2,4-D and 2,4,5-T for control of broadleaved weeds in lawns, pastures, cereal crops, and brush growth along highways and fences.
2. The organic phosphorus compounds, composed of phosphorus, oxygen, carbon and hydrogen, are used principally as insecticides and miticides. Parathion, malathion, phosdrin and tetraethyl pyrophosphate (TEPP) are examples.
3. Other organic compounds include the carbamates, dinitrophenols, organic sulfur compounds, organic mercurials, and such natural products as rotenone, pyrethrum, nicotine, strychnine and the anticoagulant rodent poisons.
4. Inorganic substances with a long history of use include copper sulfate, arsenate of lead, calcium arsenate, compounds of chlorine and fluorine, zinc phosphide, thallium sulfate and sodium fluoroacetate.

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B. DISTRIBUTION AND PERSISTENCE IN THE ENVIRONMENT

The world-wide use of pesticides has substantially increased since the development of DDT and other chlorinated hydrocarbons in the early 1940's. United States production and use are illustrated in figures 1 and 2. It is estimated that 350 million pounds of insecticides alone were used in the United States during 1962. They are distributed annually over nearly 90 million acres (about 1 acre out of 20 within the 48 contiguous states). These acreages are composed of farmlands, forests and insect breeding areas, including wetlands. Weed killers are distributed on approximately the same number of acres, with some overlap of areas covered by insecticides. Thus the land area treated with pesticides is approximately 1 acre of 12 within the 48 states. About 45 million pounds are used each year in urban areas and around homes, much of this by individual home owners. The annual sale of aerosol "bug bombs" amounts to more than one per household. Other compounds such as fungicides, also are used in substantial tonnage.

In recent years we have recognized the wide distribution and persistence of DDT. It has been detected at great distances from the place of application and its concentration in certain living organisms has been observed. DDT has been found in oil of fish that live far at sea and in fish caught off the coasts of eastern and western North America, South America, Europe and Asia. Observed concentrations have varied from less than 1 part per million (ppm) to more than 300 ppm in oil.

Residues of DDT and certain other chlorinated hydrocarbons have been detected in most of our major rivers, in ground water, in fish from our fresh waters, in migratory birds, in wild mammals and in shellfish. Small amounts of DDT have been detected in food from many parts of the world, including processed dairy products from the United States, Europe, and South America. The amounts are rarely above Food and Drug Administration (FDA) tolerance limits but these have probably contributed to the buildup of DDT we now observe in the fat of the people of the United States, Canada, Germany and England. In the United States, DDT and its metabolites have been found in the fat of persons without occupational exposure at an average of 12 ppm (approximately 100 to 200 mg. of DDT per adult) for the past 10 years. In England and Germany, recent studies revealed an average concentration of 2 ppm in human fat. Data about children are not available.

An important characteristic of several commonly used pesticides is their persistence in the environment in toxic form. The chemical half-life of stable chlorinated hydrocarbons in soils, and the time they remain active against some soil insects are measured in years. The organic phosphorus compounds are more rapidly degraded although, under certain circumstances, they have persisted from one growing season to the next following routine application. Pyrethrum, rotenone, and nicotine are destroyed relatively rapidly after application, but compounds incorporating copper, lead, and arsenic are persistent.

The distribution and persistence of other chlorinated hydrocarbons have been studies in less detail, although some of these chemicals have been widely applied. One of these, dieldrin, resembles DDT in stability, persistence, and in solubility. Recently, it has been found in the fat of residents of [p. 5] southern England. It has also been found in many wild birds, fish and mammals in the United States. These facts led the Panel to anticipate that surveys will discover dieldrin and other persistent chlorinated hydrocarbons in man and wildlife throughout most of the United States.

C. BIOLOGICAL EFFECTS ON MAN AND ANIMALS

1. *Exposure of man*

The extent of hazard associated with use of a pesticide is determined by the degree of exposure and the compound's toxicity. Exposure depends on persistence, the amount applied, the method of application, and availability of the chemical in a biologically active form. Pesticides can enter the body by (a) ingestion, (b) absorption through the intact skin, and (c) inhalation.

(a) When examining the potential hazards to man from extensive use of pesticides, an early consideration should be the possible effects of chemical residues in the nation's food supply. The Panel has received evidence that, before pesticides are recommended for registration, considerable research has been performed on the extent and nature of their residues on foods, and that safeguards exist which can permit pesticide usage without danger to the consumer. These include proper controls over manufacture, commercial distribution, and techniques of pesticide application to crops; strict establishment of tolerance limitations; inspection for residues in produce; and other precautions. When measured in foods entering interstate or foreign commerce, and in total diet studies, residue levels have been very low and rarely above the legal tolerance limits. If illegal residues are found, the foods containing them are removed from the market.

Residues are not so consistently low for food items marketed within their state of origin. Some state authorities sample food for pesticide residues. Data from certain states have shown residues well above the Federal tolerance on 3 percent of the fresh fruits and vegetables offered for sale in wholesale markets. Many states do not perform systematic sampling for residues in the produce and dairy products intended for consumption within the state.

Residues of several chlorinated hydrocarbons have been measured in game birds and game fish at levels above Federal tolerance limits. Because few wildlife meals are consumed, this is not an important source for residue accumulation in man. By contrast, household use of pesticides with inadvertent contamination of dishes, utensils, or food may well produce more significant residues in man.

(b) Most insecticides are readily absorbed through the intact skin. Skin contamination can be an important source of exposure for persons who mishandle pesticides in their formulation or commercial application. Furthermore, since householders usually take few precautions in their home and garden uses of these chemicals, they may receive extensive skin contact both from successive applications and from continuing exposure to residues.

The rate of absorption through the skin depends on the chemical nature of the pesticide and on its formulation. In general, compounds in solution in oils or in organic solvents are absorbed more readily than those

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in aqueous preparations or in dry powder. Skin absorption can occur from pesticide aerosols, from dusts, from clothing or blankets impregnated with chlorinated hydrocarbons and from contaminated soil or lawn grass.

The rates of skin absorption have not been adequately studied in man. It is particularly important to determine the rates at which mothproofing insecticides are absorbed through human skin in contact with impregnated clothing or blankets. Such impregnation is performed during the manufacture of mothproofed garments and materials, and routinely during drycleaning. Many of these articles, such as sweaters and blankets, may be in direct contact with the skin for prolonged periods. Clearly, studies are needed to understand possible sensitization and allergic responses.

(c) Man's exposure to pesticides can also occur through inhalation. Airborne insecticides are sources of exposure when released during fogging operations directed against nuisance insects in public areas, buildings, and homes. Pesticides may be inhaled in dusts from treated soil, from house dusts contaminated by applications for household pests, or from mothproofed rugs and blankets.

2. *Effects on Man*

There have been few systematic studies of people occupationally exposed to pesticides. In one such investigation, a small group of volunteers with an intake up to 35 mg. of DDT per day over a period of months was reported to show no apparent ill effects during 18 months of gross observation. DDT and its metabolites averaged 270 ppm in their fat, more than 20 times the average level found in adults sampled in this country. Limited groups of adults occupationally exposed to the more toxic pesticides are also being studied, and there is evidence of neurologic impairment, usually reversible, in those individuals heavily exposed to certain chlorinated hydrocarbons and organic phosphates. Unfortunately, possible long term effects of other compounds cannot be predicted on the basis of experience with DDT, or even predicted for DDT itself, on the basis of the limited clinical studies available.

Accidental acute poisoning in man has been caused by about 50 pesticides, including at least one compound from each major class. Each year, approximately 150 deaths are attributed to misuse of pesticides in the United States. About half of these occur in children who were accidentally exposed at home. The number of non-fatal poisonings can only be estimated. A Special Committee on Public Policy Regarding Agricultural Chemicals, appointed by Governor Edmund G. Brown on June 15, 1960, reported that in California, which uses 20% of the nationally consumed pesticides, 3,000 children per year ingest various amounts of these compounds. In that state during 1959 there were also 1,100 cases of occupational disease due to agricultural chemicals, mostly among agricultural workers. These figures include acute illnesses, whether the reaction was very mild, or severe enough to require hospitalization. One difficulty in estimating the incidence of poisoning is that the symptoms caused by pesticide toxicity are little different from those of many common illnesses.

Little is known about the consequences to man when he accumulates more than one pesticide in his body. Synergism, or potentiation, is the joint action of two agents which results in an effect which is greater than the sum

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of their individual effects. Some combinations of two organic phosphates have produced effects ten times those observed when either compound was fed separately. Preliminary FDA data show only additive effects from mixtures of chlorinated hydrocarbons included in diets of experimental animals.

Physicians are generally unaware of the wide distribution of pesticides, their toxicity and their possible effects on human health. Diagnosis of pesticide toxicity is apparent when a patient with acute asthma has to be resuscitated in the middle of the night following exposure to commercial fogging. However, diagnosis is difficult in patients with nonspecific symptoms that may result from unsuspected contamination with pesticides. The Panel was unable to find any Federally sponsored research in this area of potential medical importance.

3. *Effects on Wildlife*

Many kinds of insect control programs have produced substantial mortalities among birds and other wildlife. Some fatalities have been the result of carelessness or nondirected use; others have followed programs carried out exactly as planned. Mortalities among birds have approached 80 percent in areas heavily treated with DDT for Dutch Elm Disease control, with heptachlor for imported fire ant control and with aldrin or dieldrin for controlling the Japanese Beetle. Fish losses have been extensive even with lower rates of application in programs such as spruce budworm control using DDT. Losses following agricultural operations are more scattered and less well documented.

Most insecticides are toxic to a wide range of animals and certain classes are consistently more susceptible than others. Insecticides tend to be more toxic to invertebrates than vertebrates, because the target insects are more closely related to other invertebrates. For example, pink shrimp have been experimentally poisoned by 0.9 parts per billion of heptachlor. Other marine organisms are also highly sensitive. The growth of young oysters has been inhibited by concentrations as low as 3 parts per 100 million of chlordane, heptachlor, or rotenone. Five other commonly used pesticides inhibit oyster growth in concentrations of 1 part per 10 million.

An entire year's production of young salmon was nearly eliminated in the Miramichi River in New Brunswick in 1954, and again in 1956. This resulted from DDT applications of one-half pound per acre for control of the spruce budworm. Stream insects, which are a most important food for young salmon, disappeared and failed to return within 2 years. Surviving young salmon were very thin. In British Columbia, mortality of coho salmon approached 100 percent in at least four major streams after the surrounding forests were sprayed with 1 pound of DDT per acre for control of the blackheaded budworm. This mortality occurred despite preventive measures to avoid treating the streams themselves.

Among vertebrates, fish are generally more sensitive than birds, and birds are more sensitive than mammals. Reptiles and amphibians vary greatly from species to species, but their susceptibilities usually fall between those of fish and birds. Variations in sensitivity may result in the elimination of certain forms from the food chain. While some organisms may be decimated, resistant organisms which survive exposure may concentrate and

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store pesticides at levels higher than those found in the environment. Such biological magnification on the part of resistant species may ultimately damage more sensitive organisms which are higher in the food chain. At Clear Lake, California, for example, waters containing 0.02 ppm of TDE produced plankton containing 5 ppm, which in turn produced fish with fat containing hundreds to thousands of parts per million. Grebes that fed on the fish died although their fat contained somewhat smaller residues than the fish.

Robin populations declined drastically after Dutch elm disease spraying in certain communities in Wisconsin and Michigan. Earthworms, resistant to DDT, fed on fallen elm leaves and accumulated substantial amounts of the pesticide. Robins, for whom worms are a principal food, fed on the worms and died.

The process of biological magnification has less impact on man because human food is produced by a two or three link chain in which the process, if recognized, can be controlled. For example, residues are permitted on feeds for domestic animals only in amounts that will not ultimately yield unacceptable levels in meat, in milk, or in other animal products. Thus, excessive levels of pesticide residues in agricultural products used for human food result only from accident or misuse, while damaging levels in the food of wild animals may be unwanted effects resulting from recommended practices. When contaminated fish and shellfish are harvested commercially, any residues they may contain are of concern to the fisherman and the consumer. Yet the commercial fisherman cannot control the sources of such contamination.

Wild animal populations are affected differently by pesticides residues than are domestic animals and man. Unlike the latter, wild animals cannot be kept from treated areas long enough for the chemical residues to degrade or otherwise dissipate. Because birds and mammals are free to range over relatively large areas, they are exposed to a variety of different compounds. Insectivorous birds are likely to be attracted to areas which dense insect populations, and may be exposed when chemicals are applied. Furthermore, birds reoccupy a depleted area very rapidly; thus a treated area may constitute a trap into which successive waves of birds move and are killed. Fish in streams are generally less mobile than birds and mammals, but they, too, may be subject to multiple exposure to pesticides. Flowing waters contaminated by accidental drifts or run-offs can affect the fish even though they do not move into treated areas.

D. TOXICITY OF SPECIFIC COMPOUNDS

1. *Chlorinated Hydrocarbons*

In very small doses (some cases less than 1 ppm) chlorinated hydrocarbons have caused liver damage to experimental animals, and in large doses they have caused acute central nervous system effects, occasionally followed by death. The mechanisms leading to these effects are unknown.

The biological effects of DDT have been studied more fully than those of other pesticides. Its toxicity to man and other mammals is low. People ingesting large amounts of DDT usually suffer no apparent ill effects. In chronic feeding experiments with rats, 5 ppm produced characteristic

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chlorinated hydrocarbon changes in the liver, but no evidence of tumor induction. Reproduction studies in rats showed that 50 ppm reduced the number of young that survived the nursing period. There was no effect on reproduction at 10 ppm. However, many useful insects and other valuable invertebrates such as shrimp, crayfish, and crabs are highly susceptible to DDT. Decimation of these useful populations may be a costly side effect of extensive applications.

Dieldrin and aldrin are many times more toxic to vertebrates than DDT. Since aldrin is converted to dieldrin in man and in the environment, a discussion of dieldrin applies to both.

Dieldrin is present in the body fat of residents of England (average 0.2 ppm) and is probably also present in the fat of the U.S. population as a result of extensive applications of the chemical in this country. There have been many cases of acute poisoning in people exposed to dieldrin in their work. Signs of intoxication involve the central nervous system, and may include electroencephalographic changes, muscle tremors and convulsions. Individuals have suffered recurrences of these symptoms after they have been free of them for more than a month following their last exposure.

Our knowledge of toxicity at lower doses comes chiefly from FDA feeding experiments in which mice were fed varying concentrations of dieldrin and aldrin in their diet. Chronic exposure to as little as 0.5 ppm produced histological liver damage while increase to 10 ppm caused a four fold increase in the frequency of liver tumors. There are virtually no data on the effects on embryonic development. In one of the few experiments known to the Panel, the feeding of dieldrin (at 0.6 mg/kg of body weight) to several pregnant dogs resulted in 100 percent mortality of 14 nursing puppies. The mothers were fed the pesticide during pregnancy but none during lactation. In another study, rats fed dieldrin at 2.5 ppm in the diet showed a significant reduction in number of pregnancies and an increased mortality in suckling young.

Although most insecticides do not kill wild mammals in the field even when they kill birds and fish, 1 to 3 lbs. per acre of dieldrin or aldrin produces high mortality among mammals in the treated areas. Dieldrin is also highly toxic to many birds, amphibia, reptiles, and fish. It reduces the reproduction of captive quail by decreasing egg production, decreasing the percentage of eggs that hatch, and increasing the mortality of chicks. Many beneficial and useful invertebrates are very susceptible.

Other chlorinated hydrocarbons in common use have shown marked acute toxicity to rats in feeding experiments. Chronic effects have been noted with chlordane and heptachlor at the lowest level fed to experimental animals. Chlordane at 2.5 ppm produced liver damage and 0.5 ppm of heptachlor epoxide produced liver damage and increased mortality in the laboratory mice. Field use also suggests high toxicity to birds and mammals. Although these substances are used in large quantities there have been no studies to determine whether they accumulate in the human population, nor are there adequate studies of their genetic, tumorigenic, teratogenic or reproductive effects in mammals or birds.

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2. *Organic Phosphorus Compounds*

Among their effects, the organic phosphorus compounds inhibit cholinesterase activity and thereby interfere with transmission of impulses from nerve to ganglion and nerve to muscle.

Most organic phosphorus insecticides have relatively high acute toxicities and have caused many fatal and nonfatal poisonings in man. In cases of poisoning, removal from exposure to the compound usually permits rapid recovery. Many of them are degraded rapidly and thus seldom persist in the environment but some, such as parathion, have persisted for months in soils and have recently been found in trace amounts in water drawn from deep wells.

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IV. PEST CONTROL WITHOUT CHEMICALS

Methods for controlling pests without the use of pesticides were known to farmers even in ancient times. Crops were planted in areas least liable to pest damage; crops were moved to virgin territory to leave the pests behind; rotation was practiced and crops that were less prone to disease were planted; if the pests came late in the season, crops were planted early, and vice versa. Many of these methods are used today.

The environment can also be modified indirectly; for example we use screens on windows to keep out mosquitoes, and flood or drain marshes to destroy their breeding areas. In certain cases parasites, predators and diseases control the pests without chemicals. In the United States and many other countries of the world parasites and predators have been successfully introduced to combat scale insects on citrus fruits, apples and sugar cane; and in Australia the myxomatosis virus was introduced to kill rabbits.

Entomologists have long been interested in the use of insect enemies for pest control. The United States Department of Agriculture has been active in this area since 1888. It has imported more than 500 species of insect destroying organisms, of which about 36 have had partial or complete success. Introduced insects have succeeded in controlling cactus in Australia and Klamath weed in the western United States. However, biological methods of insect control have received relatively little attention in the United States by comparison with the great emphasis on chemical control.

An effective method of biological control is the discovery or breeding of resistant varieties of crops. This method has worked best for plant diseases, and several varieties of wheat which are resistant to rust have been bred in this country. Another example of the use of plant resistance was provided by the grafting of French wine grapes to resistant American rootstocks when the French grapes were severely damaged by the root insect Phylloxera in the middle of the last century.

Other examples of effective biological control can be cited, but success has not been frequent. Continued and extensive searches will undoubtedly yield more, and the Panel believes this approach should be expanded.

Although non-chemical methods for pest control are intriguing they also have weaknesses. Two are particularly important. In the first place, parasites and predators have adjusted over the millenia to a dynamic balance with their hosts such that they kill some but not all of them; complete host destruction would eliminate the parasite or predator by destroying its food supply. Thus, control of the pest is seldom complete enough to prevent economic damage. Furthermore, reduction of the pest population is rarely sufficient to prevent its becoming dense again. A second limitation to the use of natural enemies is that the host may become resistant, just as it may develop resistance to chemical controls.

Australian rabbits for example, are becoming resistant to myxomatosis, and their populations once again are on the increase.

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A new method of biological control is the laboratory production of sterile male insects in very large numbers, using either gamma rays or specific chemical sterilants. The males are then liberated into the natural population where their matings produce infertile eggs. Although this procedure eliminated the screw worm fly in Florida, it has not yet been investigated extensively for controlling other insects.

A still newer method is the use of sex attractants to lure male insects into traps and thus their death. With certain species this technique has great promise and developmental research is being expanded.

The variety of methods that has proven useful for biological control of certain pests, and the indication of potential value for others lead to the conclusion that more active exploration and use of these techniques may yield important benefits for the national economy and for the protection of health.

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V. THE ROLE OF GOVERNMENT IN PESTICIDE REGULATION

A. MECHANISMS FOR REGULATION

Public interest in the protection of the nation's health and its resources has led to the enactment of legislation and the establishment of administrative procedures to regulate the marketing and use of pesticides. The Public Health Service has general responsibilities for the health of man and the Fish and Wildlife Service for the protection of wild animals. In addition, two fundamental laws, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Food, Drug, and Cosmetic Act, assign responsibility for pesticide control to the U. S. Department of Agriculture (USDA) and responsibility for the safety of foods containing pesticide residues to the Department of Health, Education and Welfare (HEW). The Secretary has delegated this responsibility to the Food and Drug Administration (FDA).

When a new pesticide is developed in an industrial laboratory an application is submitted to USDA requesting that it be registered for use. If the proposed use does not include application on a food crop, USDA reviews the experimental data submitted with the application. The compound is registered for use if it is concluded that no undue hazard to man and domestic animals is associated with the proposed use when applied according to the instructions on the label.

When a pesticide is proposed for use on food crops, the application for registration must list each crop on which it is to be applied and must present the necessary data on effectiveness and toxicity. If it can be demonstrated to USDA that the produce leaves no residue on a particular crop when used in the proposed manner, the specific pesticidal formulation covered by the application is registered for use on that crop on a "no residue" basis. The product may then be legally shipped in Interstate Commerce. If, however, the compound leaves a residue, USDA delays registration until a residue tolerance has been established by FDA.

To initiate this procedure, the manufacturer files a petition for tolerance with FDA. The USDA then certifies to FDA that the product under consideration is useful and offers an opinion on whether the petitioner's proposed tolerance reasonably reflects the residues to be expected from its use according to directions. Until 1955, tolerances were established by FDA on the basis of testimony presented in public hearings. Present law requires the petitioner to present FDA with experimental evidence on toxicity to establish what tolerances, if any, will be safe, to show that the tolerances can be met under the practical conditions of the pesticide use and to provide practical methods of analysis for enforcement of the tolerances.

The concept of "zero tolerance" should be distinguished from that of "no residue." "No residue" is a determination by USDA, based on experimental data, that none will remain from a particular pesticide use, irrespective of toxicity. "Zero tolerance" is an FDA prohibition of any residue on a crop because the compound is too toxic to permit a residue. The concepts of "zero tolerance" and the "no residue" registration have been modified as more sensitive detection methods become available. In practice

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"zero tolerance" is interpreted by FDA in some cases to include a detectable level of residue, lower than that believed to be pharmacologically significant.

In addition to toxicity data, the petitioner must also submit information on the chemistry of the compound, reference to related uses and residue measurements on the crop involved. If the raw agricultural product is to be used for animal feed, data must be submitted on residues in meat and milk. A method of analysis suitable for enforcement purposes also must be submitted.

When a tolerance has been set by FDA, USDA registers the pesticide which can then be marketed with approved labeling. No pesticide can be shipped in interstate and foreign commerce without USDA registration; however, by law USDA must grant registration "under protest" upon written demand of a petitioner subsequent to registration refusal by USDA. At present, the purchaser cannot distinguish such a product from one which has been accepted for registration because the label does not carry any indication of its unsanctioned status.

A pesticide registration must be renewed every five years. Within that interval petitioners may apply for increased tolerances or for extension of existing tolerances to additional crops. Similarly, FDA may alter residue tolerances if new information warrants. Lower tolerances are not set unless the FDA believes it could prove in court that the hazard is greater than formerly determined.

The Food and Drug Administration is responsible for establishing safe tolerances of pesticide residues on food products and for enforcing such tolerances by preventing illegal residues on interstate and foreign food shipments. The Department of Agriculture has sole responsibility for approving registration for pesticide use on any agricultural product other than food crops, on food crops where no residue results, and for all nonagricultural uses.

Both USDA and FDA have enforcement programs. The USDA is responsible for insuring that the marketed pesticides are properly labeled. The FDA is responsible for insuring that tolerances are not exceeded. In addition, individual states may directly control pesticides uses, and enforce their own tolerances for produce sold within the state.

B. ADEQUACY OF PESTICIDE CONTROL

Federal laws and administrative practices relating to pesticides are intended to assure both efficacy of the product and safety to the purchaser, user, and the public. Decisions on efficacy appear to be based on reliable evidence. Experiments are well designed, meaningful controls are used, sample sizes are adequate, and conclusions reached are supported by

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the data obtained. However, efficacy alone is not an adequate criterion for judgment. Unless a pesticide proposed for registration is equally effective in a less hazardous way than methods already available, the Panel believes registration should be considered conservatively. As a corollary to cautious registration of new pesticides, more hazardous compounds might well be removed from the market when equally effective and less hazardous substitutes are found. The Panel believes that it is necessary to modify the use of some especially hazardous and persistent materials now registered.

The Panel has found that decisions on safety are not as well based as those on efficacy despite recent improvements in the procedures required by the Federal Food, Drug and Cosmetic Act for the establishment of safe tolerances for pesticide residues on food. Until 1954, the evidence of safety was submitted in the form of testimony at public hearings, and tolerances were established when the evidence appeared to support the application. At that time, the manufacturer was not required to provide an analytical method for the practical enforcement of the tolerance. Moreover, FDA has no subpoena power to require testimony not voluntarily offered. Amendments of the Act in 1954 materially improved these procedures. In addition to requiring the submission of data on chemistry, toxicology, and residues, it also required the petitioner to provide a practical analytical method for use in enforcement. The result was the provision of more data from animal experiments and, in some cases, information on human pharmacology.

As an administrative principle, tolerances are set by FDA at 1/100 of the lowest level which causes effects in the most sensitive test animals whenever data on human toxicity are not available. However, tolerances have been set for some compounds such as dieldrin, aldrin, heptachlor (epoxide) and chlordane, although a "no effect" level in animals has never been determined. After reviewing the data on which tolerances are based, the Panel concludes that, in certain instances, the experimental evidence is inadequate. Recent review by FDA has also demonstrated several such examples and the tolerances are being reassessed.

The Panel believes that all data used as a basis for granting registration and establishing tolerances should be published, thus allowing the hypotheses and the validity and reliability of the data to be subjected to critical review by the public and the scientific community.

The FDA has responsibility only for setting tolerances for pesticides which remain on foods. Decisions on all the other uses of these compounds and registration for all other compounds are the responsibility of USDA. Thus the Department of Agriculture regulatory staff evaluates and approves uses that bring pesticides into intimate contact with people, such as mothproofing of clothes and blankets, and applications to households, lawns, and gardens. The Panel believes that decisions on registrations, clearly related to health, should be the responsibility of the Department of Health, Education and Welfare.

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Current registration procedures are primarily intended to protect people and domestic animals from damage by pesticides. The protection of fish and wildlife resources will require affirmation of this intent by Congress. Following such action by the Congress, the Panel believes the Secretary of the Interior should actively participate in review of all registrations that may affect fish and wildlife.

Federally operated or supported programs are subject to review by the Federal Pest Control Review Board. In addition, an Interdepartmental Committee on Pest Control exchanges information regarding control programs. An Armed Forces Pest Control Board provides liaison and coordination within the Department of Defense and regulates sales of pesticides in military stores. There are no provisions for federal control of use after sale except in federal programs and by indirect means such as enforcement of residue tolerances.

The Federal Pest Control Review Board was established in 1961 through joint actions of the Secretaries of Agriculture, Interior, Defense, and Health, Education and Welfare, and is composed of representatives from each of these Departments. Technical matters are referred to staffs within the agencies for consideration and advice, and occasionally to the Interdepartmental Committee on Pest Control. The Board has not used consultants from outside the Government. The basic responsibility for Federal pest control operations is placed by statute in various departments and agencies. The fact that these same agencies constitute the Federal Pest Control Review Board restricts the Board's effectiveness in reviewing the programs of member agencies. The Board carefully considers programs before giving clearance and, when appropriate, offers recommendations for altering proposed procedures. Although many programs have been modified as a result of such reviews, particularly by the incorporation of additional safeguards, the discontinuation of a program has not been recommended.

More than half of the insecticides used in Federal programs are applied for the control of pests introduced from foreign areas. Quarantine is a first defense, but there are opportunities for pests to spread. Through prompt action, the Mediterranean Fruit Fly has been eradicated on three occasions during the last 33 years, following introduction into Florida. In these cases, prompt eradication of the fly prevented its spread and the need for more extensive use of chemicals.

Although eradication of a pest population is a laudable goal, it is seldom realistic. Control programs by contrast, apply pesticides in less volume, to a smaller land area, with fewer undesirable side effects at any one time, yet produce the same economic results. The gypsy moth, fire ant, Japanese Beetle, and white-fringed beetle programs, which have been continued for years, are examples of failures of the "eradication" approach. The acceptance of a philosophy of control rather than eradication does not minimize the technical or economic importance of a program, but acknowledges the realities of biology. As new control techniques such as male sterilization or highly specific attractants are developed for practical use, the elimination of some of our alien pests may become technically and economically feasible.

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In 1962, the Federal Government supported control programs involving the application of pesticides to more than 4 million acres, at a cost of about 20 million dollars. Although the Federally supported programs represent only a small part of the total national use of pesticides, individual programs may involve thousands of acres of populated urban areas.

The Panel feels that Federal programs should be models of correct practice for use in the guidance of states, localities and private users. They should, therefore, be conducted not only with attention to maximum effect on the target organisms, but with further evaluation of the associated hazards. It would, in these terms, be reasonable to expect that every large-scale operation be followed by a complete report which would appear in the public literature.

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VI. RECOMMENDATIONS

The Panel's recommendations are directed to: an assessment of the levels of pesticides in man and his environment; to measures which will augment the safety of present practices; to needed research and the development of safer and more specific methods of pest control; to suggested amendments or public laws governing the use of pesticides; and to public education.

A. IN ORDER TO DETERMINE CURRENT PESTICIDE LEVELS AND THEIR TRENDS IN MAN AND HIS ENVIRONMENT, IT IS RECOMMENDED THAT THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

1. Develop a comprehensive data gathering program so that the levels of pesticides can be determined in occupational workers, in individuals known to have been repeatedly exposed, and in a sample of the general population. As a minimum, the survey should include determinations on fat, brain, liver and reproductive organs in adults and infants; examinations to determine if placental transmission occurs; and determination of levels which may be excreted in human milk. These studies should use samples sufficiently large and properly drawn to obtain a clear understanding of the manner in which these chemicals are absorbed and distributed in the human body.

2. Cooperate with other departments to develop a continuing

network to monitor residue levels in air, water, soil, man, wildlife, and fish. The total diet studies on chlorinated hydrocarbons initiated by the Food and Drug Administration should be expanded. These should, for example, include data on organophosphates, herbicides and the carbamates in populated areas where they are widely used.

3. Provide Federal funds to assist individual states to improve their capabilities for monitoring pesticide levels in foods which are produced and consumed within the state.

B. IN ORDER TO AUGMENT THE SAFETY OF PRESENT PRACTICES, IT IS RECOMMENDED THAT

1. The Food and Drug Administration proceed as rapidly as possible with its current review of residue tolerances, and the experimental studies on which they are based. When this review is completed, it is recommended that the Secretary of Health, Education and Welfare select a panel from nominations by the National Academy of Sciences to revaluate toxicological data on presently used pesticides to determine which, if any, current residue tolerances should be altered. Of the commonly used chemicals attention should be directed first to heptachlor, methoxychlor, dieldrin, aldrin, chlordane, lindane, and parathion because their tolerances were originally based upon data which are in particular need of review. Upholding the same standards, the Secretary should ensure that new compounds proposed for registration be rigorously evaluated.

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2. The existing Federal advisory and coordinating mechanisms be critically assessed and revised as necessary to provide clear assignments of responsibility for control of pesticide use. The Panel feels that the present mechanisms are inadequate and that it is necessary to provide on a continuing basis for:

(a) Review of present and proposed Federal control and eradication programs to determine if, after consideration of benefits and risks, some programs should be modified or terminated.

(b) Development and coordination of a monitoring program conducted by Federal agencies to obtain timely, systematic data on pesticide residues in the environment.

(c) Coordination of the research programs of those Federal agencies concerned with pesticides.

(d) Initiation of a broad educational program delineating the hazards of both recommended use and of the misuse of pesticides.

(e) Review of pesticide uses and, after hazard evaluation, restriction or disapproval for use on a basis of "reasonable doubt" of safety.

(f) A forum for appeal by interested parties.

3. The National Academy of Sciences-National Research Council be requested to study the technical issues involved in the concepts of "zero tolerance" and "no residue" with the purpose of suggesting legislative changes.

4. The Secretaries of Agriculture, Interior, and Health, Education and Welfare review and define their roles in the registration of pesticides that are not present on food, but that may impinge on fish and wildlife or come into intimate contact with the public.

5. The accretion of residues in the environment be controlled by orderly reduction in the use of persistent pesticides.

As a first step, the various agencies of the Federal Government might restrict wide scale use of persistent insecticides except for necessary control of disease vectors. The Federal agencies should exert their leadership to induce the states to take similar actions.

Elimination of the use of persistent toxic pesticides should be the goal.

C. RESEARCH NEEDS

1. In order to develop safer, more specific controls of pests, it is recommended that government sponsored programs continue to shift their emphasis from research on broad spectrum chemicals to provide more support for research on:

a. Selectively toxic chemicals [p. 20]
b. Non-persistent chemicals
c. Selective methods of application
d. Non-chemical control methods such as the use of attractants and the prevention of reproduction.

In the past few years, the Department of Agriculture has shifted its programs toward these specific controls. The Panel believes this trend should be continued and strengthened. Production of safer, more specific and less persistent pesticide chemicals is not an unreasonable goal; but its attainment will require extending research efforts beyond empirical approaches to more fundamental studies of subjects such as: The mode of action of pesticides; comparative toxicology; the metabolism of compounds in insects, plants, and higher animals; and the processes of chemical degradation and inactivation in nature. Such studies will also provide the information necessary to control those pests which are rapidly becoming resistant to currently available chemicals. Intensified effort is needed in the search for selective methods of pesticide application. Compounds are often applied in excessive quantity or frequency because of such inefficiencies as drift, uneven coverage, or distribution methods insufficiently specific to reach the target pest.

2. Toxicity Studies Related to Man. The toxicity data upon which registrations and tolerances are based should be more complete and of higher quality. Although data are available on acute toxic effects in man, chronic effects are more readily demonstrated in animals because their generation time is shorter, and thus the natural history of pesticide effects is telescoped chronologically. However, there will continue to be uncertainties in the extrapolation from experimental animals to man, and in the prediction of the nature and frequency of effects in humans on the basis of those observed in other forms of life.

The Panel recommends that toxicity studies include determination of:

a. Effects on reproduction through at least two generations in at least two species of warm-blooded animals. Observations should include effects on fertility, size and weight of litter, fetal mortality, teratogenicity, growth and development of sucklings and weanings.

b. Chronic effects on organs of both immature and adult animals, with particular emphasis on tumorigenicity and other effects common to the class of compounds of which the test substance is a member.

c. Possible synergism and potentiation of effects of commonly used pesticides with such commonly used drugs as sedatives, tranquilizers, analgesics, antihypertensive agents and steroid hormones, which are administered over prolonged periods.

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3. Toxicity Studies Related to Wildlife. The Panel recommends expanded research and evaluation by the Department of the Interior of the toxic effects of pesticides on wild vertebrates and invertebrates.

The study of wildlife presents a unique opportunity to discover the effects on the food chain of which each animal is a part, and to determine possible pathways through which accumulated and, in some cases, magnified pesticide residues can find their way directly or indirectly to wildlife and to man.

4. Amplification of Research Resources. Only by stimulating training and basic investigation in the fields of toxicology and ecology are research needs likely to be met. An increased output of basic research data and a continuing supply of capable research

personnel could be ensured by a system of grants and contracts. Training grants, basic research grants, and contracts to universities and other nongovernmental research agencies funded by the Departments of Agriculture, Interior, and Health, Education and Welfare would stimulate this research. In order to accelerate immediate progress, it might prove useful to explore the contributions which can be made by competent research people and their facilities in other countries.

D. IN ORDER TO STRENGTHEN PUBLIC LAWS ON PESTICIDES, IT IS RECOMMENDED THAT AMENDMENTS TO PUBLIC LAWS BE REQUESTED. THESE SHOULD

1. Eliminate "Protest" registrations. The Panel concurs with the Department of Agriculture that these technically evade the intent of the public laws. Industry needs an appeal mechanism, however, to protect it from arbitrary decisions. Public hearings could be held on such appeals.

2. Require that every pesticide formulation carry its official registration number on the label. The Department of Agriculture has recommended such an amendment as a means of increasing the protection of the consumer.

3. Clarify the intent of the Federal Insecticide, Fungicide, and Rodenticide Act to protect fish and wildlife by including them as useful vertebrates and invertebrates.

4. Provide, as a part of the operating budgets of Federal control and eradication programs, funds to evaluate the efficiency of the programs and their effects on nontarget organisms in the environment. Results of these studies should be published promptly.

Approximately 20 million dollars were allocated to pest control programs in 1962, but no funds were provided for concurrent field studies of effects on the environment. The Department of Agriculture has repeatedly suggested that other interested agencies participate in the general programs, but funds have not been available except by diversion from other essential agency functions.

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E. TO ENHANCE PUBLIC AWARENESS OF PESTICIDE BENEFITS AND HAZARDS, IT IS RECOMMENDED THAT

The appropriate Federal departments and agencies initiate programs of public education describing the use and the toxic nature of pesticides. Public literature and the experiences of panel members indicate that, until the publication of "Silent Spring" by Rachel Carson, people were generally unaware of the toxicity of pesticides. The government should present this information to the public in a way that will make it aware of the dangers while recognizing the value of pesticides.

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PANEL ON THE USE OF PESTICIDES

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Jerome B. Wiesner, Chairman, Special Assistant to the President for Science and Technology, The White House.

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4.2b DEFICIENCIES IN ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, HOUSE COMMITTEE ON GOVERNMENT OPERATIONS

H.R. REP. No. 91–637, 91st Cong., 1st Sess. (1969)

DEFICIENCIES IN ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

NOVEMBER 13, 1969.—Committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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Mr. DAWSON, from the Committee on Government Operations, submitted the following

ELEVENTH REPORT

[To accompany 11th report on deficiencies in administration of Federal Insecticide, Fungicide, and Rodenticide Act]

BASED ON A STUDY BY THE INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

On November 12, 1969, the Committee on Government Operations approved and adopted a report entitled "Deficiencies in Administration of Federal Insecticide, Fungicide, and Rodenticide Act." The chairman was directed to transmit a copy to the Speaker of the House.

INTRODUCTION

Under the rules of the House of Representatives, the Committee on Government Operations has responsibility for studying the operation of Government activities at all levels from the standpoint of economy and efficiency. The committee also has responsibility for receiving and examining reports of the Comptroller General of the United States. These responsibilities, insofar as they relate to the Department of Agriculture, the Department of Health, Education and Welfare, and a number of other agencies, have been assigned by the committee to the Intergovernmental Relations Subcommittee. In accordance with this assignment, the subcommittee has ben examining the administration of the Federal Insecticide, Fungicide, and Rodenticide Act.

The subcommittee began its investigation of this subject area late in 1968, after receiving a report from the Comptroller General concerning "Need to Improve Regulatory Enforcement Procedures Involving Pesticides" which disclosed the existence of serious deficiencies in the operations of the Pesticides Regulation Division of the Depart- [p. 1] ment of Agriculture's Agricultural Research Service. The subcommittee's investigation and a second report by the Comptroller General revealed further serious deficiencies and led to preparation of this report.

The subcommittee held public hearings on May 7 and June 24, 1969, with testimony from the following officials of the Department of Agriculture and the Department of Health, Education, and Welfare:

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Dr. Ned D. Bayley, Director, Science and Education.

Agricultural Research Service

Dr. George W. Irving, Jr., Administrator.

Dr. Robert J. Anderson, Associate Administrator.

Dr. Harry W. Hays, Director, Pesticides Regulation Division.

Lowell E. Miller, Assistant Director for Enforcement, Pesticides Regulation Division.

Harold G. Alford, Assistant Director for Registration, Pesticides Regulation Division.

Anthony J. Dellavecchia, Head, Inspection Services and Accident Investigation, Pesticides Regulation Division.

Office of the General Counsel

Charles W. Bucy, Assistant General Counsel for Marketing, Regulatory Laws, Research and Operations.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

R. E. Duggan, Deputy Associate Commissioner for Compliance.

Dr. T. H. Harris, Chief, Division of Pesticide Registration, Office of Product Safety.

Lessel L. Ramsey, Assistant Director for Regulatory Programs, Bureau of Science.

Office of the General Counsel

William W. Goodrich, Assistant General Counsel, Food, Drug, and Environmental Health Division.

Testimony at the hearings was supplemented by data furnished for the record. Additional information was obtained by the subcommittee staff through interviews with personnel of the agencies concerned and through examination of material in their files. The subcommittee investigation was concentrated on administration of the Federal Insecticide, Fungicide, and Rodenticide Act and related statutes; it did not extend to questions such as the long-range effect of persistent pesticides on the environment.

ACKNOWLEDGMENT

The subcommittee wishes to express its appreciation for the assistance provided by the General Accounting Office in connection with its investigation. The subcommittee particularly appreciates the contribution made by Mr. Morton A. Myers and Mr. Richard E. Chervenak of the GAO staff.

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SUMMARY

Federal regulation of pesticides

Since 1947, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has required that all pesticides shipped in interstate commerce be registered with the U.S. Department of Agriculture (USDA). To qualify for registration, a pesticide must be both safe and effective when used as directed. The act provides criminal penalties for the interstate shipment of pesticide products which are unregistered, adulterated or misbranded. Under the act, a pesticide is "misbranded" if its labeling contains false or misleading statements or if it does not bear clearly understandable warning statements adequate if complied with to prevent injury and protect the public. USDA is authorized by the act to initiate court proceedings for seizure of pesticides which violate the act.

A pesticide registration may be canceled at any time, in accordance with procedures specified in the act, if it does not appear that the product or its labeling comply with provisions of the act. A registration may also be canceled if it is not renewed every 5 years. A registration may be suspended immediately if the Secretary of Agriculture determines such action is necessary to prevent an imminent hazard to the public.

The Federal Food, Drug, and Cosmetic Act requires establishment of a tolerance by the Food and Drug Administration (FDA) in the event a registered use of a pesticide will leave a residue on food; in the absence of a tolerance (or an exemption from the tolerance requirement) food containing a pesticide residue is considered adulterated.

Primary responsibility for carrying out provisions of FIFRA is assigned to the Pesticides Regulation Division (PRD), a unit of USDA's Agricultural Research Service (ARS). Within PRD, administrative details and records relating to registration applications and cancellation proceedings are handled by the Registration Branch, although product evaluation staffs are responsible for making final decisions concerning approval of applications or cancellation of registrations. The Enforcement Branch is responsible for conducting activities necessary to effectively regulate marketing of pesticides, including inspection, sampling and laboratory analysis of products in marketing channels, seizure and recall actions, and preparing cases for criminal prosecution.

PRD specialists review data submitted by manufacturers or formulators of products proposed for registration in order to determine the safety and effectiveness of such products, and the adequacy of proposed label warnings and directions. If the data submitted is not considered sufficient, more information is requested. Under a 1964 interdepartmental agreement, pesticide labels submitted for registration are reviewed by the Department of Health, Education, and Welfare (HEW) from the standpoint of possible effects of the pesticide on human health and the Department of Interior in terms of the effect on fish and wildlife.

More than 45,000 products involving some 900 different chemical compounds are currently registered.

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GAO criticism of enforcement procedures

In September 1968, the General Accounting Office (GAO) issued a highly critical report concerning enforcement procedures followed by PRD through mid-1967. The report included the following disclosures:

(1) When its inspectors found a potentially hazardous or ineffective product, it was PRD practice to take seizure action against only the quantity of pesticide at the location where the sample was obtained. No action was taken to locate and remove from the market additional quantities of the same product being held for sale at other locations, although FIFRA authorizes access to shipping records for this purpose.

(2) Despite evidence of repeated violations by some shippers, PRD had not initiated a single criminal prosecution for 13 years. Moreover, it had no procedures for determining under what circumstances such action would be taken.

(3) Notices of judgments obtained in actions (primarily seizures) instituted under FIFRA had not been published as required by the act.

Subcommittee investigation

The subcommittee began its investigation shortly after receiving the GAO report. At the same time, the GAO continued work on a second report dealing with PRD's registration of certain products containing lindane. In the second report, issued in February 1969, the GAO found that PRD had continued to register lindane products for use in continuous vaporizers in restaurants and other commercial and industrial establishments for many years, despite repeated objections by the Public Health Service (PHS) and other public and private organizations, without resolving the safety questions involved.

Subcommittee hearings were held on May 7 and June 24, 1969. At the hearings, USDA officials acknowledged the accuracy of the GAO reports and stated that the reports had been helpful.

Changes in enforcement procedures

Testimony at subcommittee hearings established that significant changes in PRD enforcement procedures and operations were made after the mid-1967 appointment of Lowell E. Miller as assistant director for enforcement. In September 1967, PRD began requesting manufacturers to voluntarily recall violative products from the market. Formal procedures for requesting voluntary recall action, to be followed by examination of shipping records and multiple seizure actions in instances where shippers refused to take voluntary action, were approved May 5, 1969. Operating guidelines for referring cases to the Department of Justice were established, and a criminal indictment was returned by a Chicago grand jury in March 1969. Steps were taken to resume publication of notices of judgment.

Other testimony disclosed that a newly formed prosecutions and import section was staffed by only one man at the professional level, who was responsible for supervising all imports of pesticides in addition to preparing cases for prosecution. PRD witnesses admitted it was unlikely that one man working part time would be able to reduce or even keep up with the backlog of cases being reviewed for prosecution.

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Claimed improvements in registration procedures

USDA witnesses acknowledged the existence of past deficiencies in registration procedures, but contended that significant improvement had been made. They attributed much of the progress claimed to the work of a 1965 task force which studied PRD and to the appointment in mid-1966 of its chairman, Dr. Harry W. Hays, as director of the Pesticides Regulation Division.

Lack of interagency cooperation

The 1964 interdepartmental agreement provides for departmental representatives to try to resolve differences, if one agency believes a registration proposal should be rejected. If agreement cannot be reached within two weeks of the initial objection, the agreement provides for the matter to be referred directly to the Secretary of the Department responsible for final action. The agreement further provides for a general conference of departmental representatives at least once each year.

Dr. Harry Hays estimated at the May 7 hearing that only about half a dozen of some 45,000 registered products had been approved by USDA over HEW objections. Further inquiry by the subcommittee disclosed that, according to USDA figures, HEW had objected to a total of 1,663 proposed registrations or reregistrations during a 5-year period from July 1, 1964, through June 30, 1969. Neither HEW nor USDA could tell the subcommittee how many of the 1,633 products objected to were actually registered, since USDA did not keep records of products registered over objections and did not inform HEW as to the action taken. However, USDA advised the subcommittee that during fiscal year 1969 alone there apparently were 185 registrations over HEW objections.

USDA witnesses admitted that not one of the 1633 HEW objections was referred to the Secretary of Agriculture in accordance with provisions of the Interdepartmental Agreement, even though the 1965 task force—headed by Dr. Hays—had called attention to the lack of compliance with this requirement. Dr. George W. Irving, ARS Administrator, took the position that ARS had "resolved" the issues involved in the objections by placing the products on the market and there consequently was no need to refer the matters to the Secretary. USDA witnesses also testified that the annual meetings required by the agreement had not been held.

Memoranda in HEW files indicate that some HEW officials concluded before the end of 1964 that PRD had no intention of complying with the terms of the Interdepartmental Agreement, and that this belief continued more or less unchanged for several years thereafter. On May 7, 1969, USDA witnesses told the subcommittee that a meeting of USDA, HEW and Interior Department representatives had been held on March 19, 1969, to try to improve interdepartmental cooperation in connection with the agreement. The meeting apparently was not completely successful, since the subcommittee subsequently located a memorandum indicating that an HEW request for information on products registered over objections had been turned down in April 1969 by Dr. Hays on the ground that the information, if provided, might be used against him.

Misconception of burden of proof [p. 5]

Until early 1964, the Federal Insecticide, Fungicide, and Rodenticide Act authorized "protest registration." Under the law, PRD was required to register a product, if the applicant insisted, even though PRD did not believe it had been shown to be safe; the product could then be removed from the market only on the basis of evidence sufficient to justify a court decision. FIFRA was amended in May 1964 to eliminate protest registration and make it clear that the burden of establishing the safety of a pesticide product must be met by the applicant before it could be registered. Although some USDA statements acknowledged that the burden of proof of safety was on the applicant, other testimony indicated that PRD had, in effect, shifted this burden by registering pesticides over objections unless the objectors could produce satisfactory evidence of hazard.

Food adulteration

Under the Federal Food, Drug, and Cosmetic Act, any food in interstate commerce which bears or contains any added poisonous or deleterious substance is considered adulterated unless a tolerance (or an exemption from the tolerance requirement) for such substance has been granted by FDA and the amount of the substance does not exceed the tolerance.

FIFRA contains no specific provision relating to contamination of food. However, the position of USDA, as reported in a 1965 study made by the National Academy of Sciences under a joint USDA–HEW contract, is that directions for use of a pesticide are not adequate to protect the public if it might leave a residue on food which would be subject to FDA action.

The subcommittee investigation disclosed that USDA had received an FDA study in 1953 which concluded that the use of lindane vaporizers in restaurants would leave residues on food. It further disclosed that USDA continued to register and reregister lindane for use in continuous vaporizers in restaurants for more than 15 years thereafter, even though no tolerance had been granted or even requested for such residues. PRD registration files for a DDVP resin strip distributed by the Shell Chemical Co. contain documents establishing that a similar situation occurred in connection with that product over a period of several years.

USDA witnesses admitted that other units of the Department of Agriculture prohibited use of lindane vaporizers and DDVP strips in food processing establishments under their jurisdiction at the same time PRD was approving registration of such products for use around food. The subcommittee investigation also disclosed that FDA had refused to approve a 1963 application for a tolerance for residues of pyrethrins and piperonyl butoxide resulting from use of a vaporizing device in food processing areas.

Basis for lindane cancellation action

USDA finally announced that it was taking action to cancel registrations of lindane products for use in continuous vaporizers on April 29, 1969, some 2 months after release of the GAO report on this subject and a few days before the subcommittee's first hearing. USDA witnesses contended that the agency's failure to act for some 16 years

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after it became aware of safety questions concerning lindane products was necessitated by a lack of scientific data establishing that the use of such products was hazardous. They claimed, moreover, that such data had not become available until very recently, despite vigorous and long-continued efforts on their part to obtain it previously. However, further inquiry by the subcommittee indicated that the data cited by PRD's medical advisors in recommending cancellation had been in PRD's hands or readily available to it for more than 2 years.

The subcommittee investigation also disclosed that when PRD finally decided to conduct its own tests after nearly 16 years, it took only 5 days to establish that use of lindane vaporizers would result in illegal residues on food. Action to require label warnings against use of DDVP strips in areas where food is prepared or served was not initiated until September 1969.

Confusing and contradictory pesticide labeling

Early stages of the subcommittee's investigation raised questions concerning the adequacy of labeling approved by PRD for a number of pesticide products. In some instances, safety warnings and directions for use appeared to be contradictory. For example, products containing thallium sulfate—a highly toxic ant and rat poison—bore warnings that the poison should be kept away from children; however, the directions for use called for the product to be placed on floors and in other places accessible to ants and rats—and obviously accessible to children. Products containing lindane and DDVP bore warnings against contamination of food, but their labels indicated they were approved for use in restaurants under conditions practically certain to result in contamination of any exposed food.

When questioned about this, Dr. Hays assured the subcommittee that products presently being approved for use were being carefully screened so that obviously contradictory labeling could no longer get by. However, the subcommittee investigation disclosed that a concentrated fly and roach spray product bearing such labeling had been approved in May 1969, a few days after the subcommittee's first hearing. In this instance, the warning notice cautioned the user to "Use in well ventilated rooms or areas only" while the directions for use began by instructing him to "Close all doors, windows and transoms."

The subcommittee investigation also disclosed that PRD had approved a label claiming that a widely advertised detergent "germproofs" in cold water, although Dr. Hays acknowledged under questioning that the product would not kill germs.

PRD advised the subcommittee that it had entered into a contract with the University of Illinois in June 1968 for a study of pesticide labeling. Preliminary reports indicate that the researchers conducting the study nave concluded that most pesticide users do not read labels and that those who do find the labels difficult to understand.

Inadequate information on pesticide poisonings

Dr. Hays told the subcommittee that PRD places considerable reliance on accident reports as a means of detecting dangerous pesticides whose potential hazards might not have been fully apparent when they were registered. The subcommittee was also informed that USDA's accident reporting system appeared to be working very well. Further inquiry disclosed that USDA received reports of 150 to 175 pesticide

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poisoning incidents during 1968. Most of these did not involve humans; the 52 that did involved a total of 163 persons.

Dr. Hays indicated it was his opinion that the reports received by USDA represented a "fair share" of the total number of pesticide poisonings occurring each year. He subsequently stated that he was unaware that the HEW National Clearinghouse of Poison Control Centers receives approximately 5,000 reports of pesticide poisonings annually and that officials of that unit believe the total number of such poisonings is 8 to 10 times the number reported to the poison control centers.

Failure to initiate cancellation actions

Since 1964, USDA has had specific authority to cancel registrations of pesticides which do not appear to comply with the provisions of FIFRA. Under the law, cancellation action must be initiated by giving notice to the registrant. Thirty days after such notice, the registration is automatically cancelled unless the registrant takes corrective action (if corrective action is possible), requests referral of the matter to an advisory committee selected by the National Academy of Sciences or asks for a public hearing. After reviewing the report of an advisory committee or the record of a public hearing, the Secretary issues an order with respect to cancellation or modification of the registration. If the registrant is dissatisfied with an order issued after an advisory committee study, he may still request a public hearing.

Although the 1964 amendments to FIFRA provided basic legal authority for cancellation proceedings, the authority could not be utilized in contested cases without rules of practice for hearings and procedures for referral of matters to advisory committees. The subcommittee investigation disclosed that such rules and procedures were not adopted until August 29, 1969. A number of requests for referrals to advisory committees or public hearings were received prior to 1969; documents in PRD files indicate that when such requests were received, efforts to pursue the cancellation action were abandoned and the product involved was simply left on the market. Insofar as the subcommittee is aware, PRD has never secured cancellation of a registration in a contested case.

The subcommittee investigation also disclosed that PRD had failed to even send cancellation notices to distributors of certain arsenic compounds, although it had decided nearly 2 years before on the basis of "numerous accidents involving children and domestic animals" that such products were too dangerous to be sold for use in or around the home.

Suspension authority used only once

FIFRA authorizes suspension of pesticide registrations when USDA finds such action is necessary to prevent an imminent hazard to the public. However, testimony at subcommittee hearings indicated that this has occurred in only one instance. PRD officials testified that registration of a DDVP strip distributed by the Aeroseal Co. had been suspended in March 1969 after representatives of Shell Chemical Co. complained that the Aeroseal product was not the same as the Shell DDVP strips even though it had been registered on that basis. Although the Aeroseal product contained the same amount of DDVP as the Shell resin strip, Dr. Hays testified that he was concerned that the

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blotter type material in which the DDVP was impregnated might permit its release in concentrations "that could produce some very serious effects." Despite his expressed concern about the Aeroseal DDVP strip, however, Dr. Hays testified that he had taken no action to require Shell to remove from the market or relabel DDVP strips being sold without a required warning against use in nurseries or rooms where infants, ill or aged persons were confined nor did he see any particular need for such action.

Lack of action to protect public from hazardous products

Although the subcommittee investigation did not disclose any instance (other than the Aeroseal matter) in which a registration had been cancelled or suspended in a contested proceeding, there were instances in which registrants more or less voluntarily agreed to cancellation of registrations for products regarded as particularly hazardous, such as those containing thallium sulfate. Testimony at subcommittee hearings disclosed that PRD had no procedures to insure that its enforcement personnel were notified when pesticide registrations were cancelled or amended for safety reasons. Moreover, testimony by Dr. Hays disclosed that he had deliberately left violative products on the market to be sold after cancellation or amendment of registrations.

While obviously necessary to protect the public, removal of hazardous pesticides from marketing channels does not prevent injury to an unsuspecting buyer who already has the product in his home. Although other units of the Agricultural Research Service apparently take prompt action to warn against possible hazards to animals from regulated products, PRD witnesses testified that there were no procedures for warning the public of specific hazards from particular pesticide products.

Federal conflict-of-interest laws

Federal conflict of interest laws prohibit Government employees, including consultants serving on an intermittent or temporary basis, from participating personally and substantially in their official capacity in matters in which they have a financial interest. The prohibition also applies to matters in which, to the Government employee's knowledge, a private organization which employs him or with which he is negotiating or has an arrangement concerning prospective employment has a financial interest. Former Federal employees are prohibited from acting as agent or attorney for anyone other than the United States in connection with matters involving a particular party or parties in which the United States is a party or has a direct and substantial interest if the former employee participated personally and substantially in the matter as a Government employee.

Appointment of Shell official to registration task force

In July 1965, the Secretary of Agriculture announced appointment of a seven-member task force, headed by Dr. Harry Hays, to study procedures used by PRD in determining the safety and effectiveness of pesticides offered for Federal registration. Dr. T. Roy Hansberry, an official of a Shell Chemical Co. research affiliate at Modesto, Calif., was the only member of the task force employed by private industry. Although Shell Chemical Co. is one of the larger producers of pesticides

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and had registered more than 160 products before the end of 1965, an as yet unidentified individual in the ARS Personnel Division noted on Dr. Hansberry's personnel clearance form that ARS:

> * * * does not have, or know of, any official business with the persons, firms, or institutions with which Dr. Hansberry has other financial interests * * * which might constitute a conflict of interest.

Failure to keep minutes of meetings

Although the subcommittee was informed that the principal reason for wanting Dr. Hansberry on the task force was so that he could review procedures, facilities, and personnel at PRD laboratories, documents located by the subcommittee indicate that Dr. Hansberry was assigned to a three-member subcommittee which reviewed criteria used by PRD in determining whether registration applications should be approved. Minutes were kept for only one meeting of the task force; they were kept by Harold Alford, a PRD staff member who had been named Executive Secretary of the task force. According to the minutes, Mr. Alford reminded the group at the close of the first meeting that there were restrictions in the law with respect to disclosure of confidential information and that this should be thoroughly understood since Dr. Hansberry was associated with private industry. At the beginning of the next meeting, Mr. Alford testified, he was told by Dr. Hays that his services would no longer be required; no minutes were kept thereafter. Although Alford's appointment had been announced by the Secretary, the subcommittee investigation disclosed no evidence that his dismissal had been approved by—or even made known to—the Secretary.

Activities of John S. Leary, Jr., relating to Shell DDVP strip registration

Documents in PRD files indicate that the initial registration of Shell's DDVP strip was approved early in 1963 after John S.

Leary, Jr., then PRD's Chief Staff Officer for Pharmacology, overruled an objection raised by one of his subordinates. PRD records also indicate that Mr. Leary participated in meetings involving the safety of DDVP strips with representatives of Shell and of Government agencies in 1964 and 1965. During this period, ARS and HEW records reflect consistent opposition by HEW personnel to the continued registration of DDVP strips and lindane and pyrethrum products for use in vaporizing devices. Late in 1965, after ARS declined to participate in a joint study, an Ad Hoc Committee was appointed by the Public Health Service to study safety questions relating to use of the above products. The Ad Hoc Committee met in Washington on November 19, 1965. All eight of its members subsequently recommended against continued use of lindane vaporizers; six of the eight also opposed DDVP strips and pyrethrin vaporizers.

In September 1966, the report of the PHS Ad Hoc Committee was sent by the Surgeon General to the Agricultural Research Service. In October, Dr. Harry Hays called a meeting of three PRD medical consultants to consider safety questions relating to the same products covered by the PHS Ad Hoc Committee report. The subcommittee investigation disclosed no evidence that the medical consultants were

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given copies of the PHS report; they were, however, given copies of a six-page memorandum on vaporized pesticides prepared for Dr. Hays by Mr. Leary. By contrast with the PHS report, the Leary memorandum did not oppose continued registration of DDVP strips.

Leary action involving DDVP after accepting Shell position

USDA records indicate that on November 14, 1966, Mr. Leary resigned, effective December 31, 1966, to accept a position with Shell Chemical Co. PRD files contain a memorandum dated December 6, 1966, from Mr. Leary to Dr. Hays reviewing the PHS report on vaporized pesticides. The Leary memorandum stated that the PHS report "serves no useful purpose" and did not justify any change in the registration status of vaporized pesticides.

Leary meets with PRD officials on behalf of Shell

In 1967 and early 1968, PRD informed Shell Chemical Co. on several occasions that a warning against use around infants, ill or aged persons must appear on the label of its DDVP strip. On July 15, 1968, representatives of Shell Chemical Co. met with Dr. Hays and Mr. Alford of PRD to argue that the requested warning was not necessary. Correspondence and documents in PRD files, as well as statements by Dr. Hays and Mr. Alford, indicate that John S. Leary, Jr., was present and took an active part. The subcommittee investigation also disclosed that Mr. Leary visited the Atlanta offices of the PHS pesticides program to discuss matters related to continued registration of Shell's DDVP strip.

Utilization of same medical consultant by PRD and Shell

The subcommittee investigation disclosed that Dr. Mitchell R. Zavon was on the rolls as a consultant to the Pesticides Regulation Division almost continuously from March 1963 until June 1969. During this entire period, Dr. Zavon apparently was also serving as a medical consultant to Shell Chemical Co.

In April 1964 and again in May 1965, when Dr. Zavon was reappointed a PRD consultant for 1-year periods, the USDA Office of General Counsel noted his connection with Shell Chemical Co. The ARS Personnel Division was asked to especially call the conflict-of-interest laws and regulations to Dr. Zavon's attention in order that any possible conflict of interest between his PRD duties and his position with Shell might be avoided.

Zavon scientific studies on DDVP

The subcommittee investigation disclosed that Dr. Zavon, individually or with others, conducted a number of scientific studies used by Shell to support its contention that DDVP was safe. A 1964 study in which food samples collected under Dr. Zavon's direction were sent to Shell laboratories in Modesto, Calif., for analysis resulted in a finding that use of DDVP strips in restaurants for 1-and 2-hour periods did not leave residues in exposed food; by contrast, studies carried out by others found that use of DDVP strips did leave residues in food.

Contacts by Dr. Zavon with Federal officials concerning DDVP

HEW records indicate that Dr. Zavon participated—presumably as a consultant to Shell—in an April 1965 meeting concerning DDVP

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with John S. Leary, Jr., two representatives of the Public Health Service, and three Shell employees.

Shell Chemical Co. had formally objected to the November 1965 PHS Ad Hoc Committee study of vaporized pesticides, arguing that the National Academy of Sciences (NAS) was the appropriate body to conduct such a study, if any were carried out. PHS had also recommended referral of the matter to NAS when it sent a copy of the ad hoc committee report to USDA in September 1966.

In August 1966, supervisory responsibility for the PHS pesticide program was transferred from Washington to the Communicable Disease Center (CDC) in Atlanta. A CDC official had been one of the two members of the ad hoc committee who favored continued registration of DDVP strips; in advocating his minority position, he had stressed that effort devoted by CDC over a period of years to promoting the use of insecticide vapors to control disease-carrying insects might be nullified by action against DDVP.

In December 1966, Dr. Zavon wrote an assistant surgeon general about the report of the ad hoc committee. Dr. Zavon endorsed DDVP "as a health officer" (he is an assistant health commissioner for the city of Cincinnati) and suggested that the entire matter of pesticide vaporizers be "re-viewed" by PHS with an opportunity for those with experience with the devices to present information concerning them. Dr. Zavon's letter—the only instance known to the subcommittee in which a health officer wrote PHS to endorse use of DDVP strips—did not mention his relationship with Shell Chemical Co.

Dr. Zavon serves as PRD consultant in meeting on DDVP

In June 1967, Dr. Zavon, in his capacity as a consultant to PRD, participated in a Washington meeting with other PRD medical advisors. The agenda for the meeting included safety questions concerning lindane and DDVP strips; minutes of the meeting indicated that these matters were discussed at some length but that no recommendations for action were made. Dr. Zavon's travel expenses for the meeting were paid by USDA.

Agreement with PHS on DDVP warning

Dr. Zavon, who had served as a medical officer in the Public Health Service from 1950 to 1957, was in frequent contact with Atlanta officials of the PHS pesticides program during the latter part of 1967. According to information supplied by Shell Chemical Co., he was responsible for reaching an agreement with PHS for withdrawal of that agency's objection to registration of DDVP strips provided a warning was placed on the label against use in rooms "continuously" occupied by infants and infirm individuals. PHS records indicate the agreement was reached in September 1967.

PRD refuses to accept proposed labeling

Shell subsequently asked PRD to approve addition of the warning statement agreed to by PHS, but PRD advised Shell that inclusion of the word "continuously" was not acceptable. Shell responded by withdrawing its request for a label change and submitting additional data which it contended established that the warning was not needed.

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Further contacts by Zavon with PHS

A memorandum in HEW files indicates that Dr. Zavon called Atlanta to advise PHS officials there that a copy of the additional data was being sent to them. According to the memorandum, the reason given by Dr. Zavon for Shell's decision not to add the warning statement was that Dr. Hays "did not see the need" for revising the label; there is no indication in the memorandum that Dr. Zavon mentioned PRD's insistence on a stronger warning statement. The memorandum also indicates that Dr. Zavon asked PHS officials to make "discreet inquiries" concerning the accuracy of a report he had heard that the President's Office of Science and Technology would review the problem of pesticide vaporizing devices.

Zavon conference with PRD officials

An August 7, 1968, letter written by Shell Chemical Co. to Dr. Harry Hays refers to a "recent conference" at which Dr. Zavon reviewed scientific data on DDVP strips for Dr. Hays. Dr. Hays told the subcommittee staff he did not remember whether Dr. Zavon was present at the July 15 meeting in which Mr. Leary participated, but that it was possible he might have been.

Shell agrees to relabel DDVP strips

After further demands by PRD that Shell add a warning statement to the label of its DDVP strip, Shell finally agreed to do so on January 8, 1969. On the same day, PRD medical consultants met in New York to again consider safety questions relating to lindane and DDVP strips. The group recommended cancellation action against lindane products, but decided to reconsider questions relating to DDVP strips at a subsequent meeting.

Question concerning dieldrin

When Dr. Zavon was initially appointed to serve as a consultant in 1963, his job description indicated that he was to advise PRD on problems involving the pesticide dieldrin. Shell Chemical Co. is a basic producer of dieldrin, and had a number of registered pesticide products containing that substance prior to and during 1963. The subcommittee investigation did not disclose whether or not Dr. Zavon actually advised USDA, as a consultant, on any matter involving dieldrin in which Shell had a financial interest.

Patent question

The subcommittee investigation disclosed that HEW announced in 1955 that PHS research scientists had discovered a new insecticide known as DDVP; the announcement stated that any domestic manufacturer who wished to do so would be free to produce DDVP. Despite these statements, however, Shell Chemical Co. now claims exclusive patent rights to DDVP.

FINDINGS AND CONCLUSIONS

1. Until mid-1967, the USDA Pesticides Regulation Division failed almost completely to carry out its responsibility to enforce provisions of the Federal Insecticide, Fungicide, and Rodenticide Act intended to protect the public from hazardous and ineffective pesticide products being marketed in violation of the act.

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Prior to mid-1967, no effort was made to systematically remove potentially hazardous or ineffective products from the market; instead, only the amount of illegal product found at the single location where a violative sample had been obtained was seized.

Not a single criminal prosecution had been initiated for more than 10 years prior to mid-1967, despite evidence of repeated violations by some shippers.

Notices of judgments obtained in seizure actions were not being published, even though publication is required by law.

Significant improvements in PRD enforcement procedures have been made since mid-1967.

In late 1967, after appointment of Lowell E. Miller as Assistant Director for Enforcement, PRD began requesting manufacturers to voluntarily recall violative products from the market.

Formal procedures for requesting recall action, to be followed by multiple seizure action if necessary, were approved in May 1969.

Operating guidelines for referral of cases to the Department of Justice have been established and an indictment has been returned in a case so referred. A Prosecutions and Import Section has been established to handle referral of cases; however, its staffing—consisting of the part-time services of only one person at the professional level—is obviously inadequate.

Publication of notices of judgment has been resumed.

2. Numerous pesticide products have been approved for registration over objections of the Department of Health, Education, and Welfare as to their safety without compliance with required procedures for resolving such safety questions.

The subcommitee investigation disclosed that HEW objected to proposed registrations for more than 1,600 pesticide products during the 5-year period ending June 30, 1969.

Many, if not most, of these products were registered for uses to which HEW had objected. The exact number is not known because PRD does not keep records of products registered over HEW objections and has failed or even refused to inform HEW of action taken with respect to its objections.

The subcommittee investigation disclosed that PRD was, in effect, demanding that HEW supply scientific proof of hazard to support its objections, rather than asking the would-be registrant to resolve any doubt by providing adequate evidence of the product's safety.

Although a 1964 interdepartmental agreement requires that unresolved HEW objections be referred to the Secretary of Agriculture for determination before a registration is approved, not one of the more than 1,600 HEW objections was so referred. A task force headed by the present PRD Director noted in a 1965 report that PRD was not complying with the agreement, but no action was taken to correct the matter.

3. The Pesticides Regulation Division has approved pesticide products for uses which it knew or should have known were practically certain to result in illegal adulteration of food.

The subcommittee investigation disclosed that PRD has registered or reregistered products such as lindane vaporizers or DDVP strips for use in restaurants or other food-handling establishments despite

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evidence that such uses would leave residues on food and despite the fact that other Federal agencies refused to permit use of the products in food-handling establishments.

Pesticide residues on food in interstate commerce constitute adulteration, unless a tolerance has been issued for such residues by the Food and Drug Administration. In the above instances, no such tolerances had been issued or even applied for. Moreover, FDA's authority to issue a tolerance for addition of a pesticide to prepared food in restaurants is questionable.

4. The Pesticides Regulation Division has failed to take adequate precautions to insure that pesticide product labels approved for registration clearly warn users against possible hazards associated with such products.

Examination of a relatively small number of pesticide products labels during the subcommittee investigation disclosed several instances where warning statements and directions for use on the same label were confusing or even directly contradictory. At least one instance where a misleading effectiveness claim has been approved and widely used was also found.

Preliminary results of a study being made under a contract with PRD indicate that most pesticide users do not read labels and those who do have difficulty understanding them.

5. Information available to Federal agencies concerning pesticide poisonings is inadequate and incomplete. The Pesticides Regulation Division has failed to make effective use of even the limited data available.

According to its Director, the Pesticides Regulation Division has placed considerable reliance on accident reports as a means of detecting dangerous pesticide products. During 1968, PRD received reports of 52 pesticide poisoning incidents involving a total of 163 persons, a figure characterized as representing a fair share of all pesticide poisonings.

The subcommittee investigation disclosed that the reports received by PRD were actually only a tiny fraction of the approximately 5,000 pesticide poisoning cases reported annually to HEW, even though the reports received by HEW were estimated to reflect only one of every eight or 10 pesticide poisonings actually occurring.

The subcommittee found no evidence that PRD has made any systematic use of the HEW reports; in fact, PRD's Director was not even aware of the volume of reports received by HEW.

6. The Pesticides Regulation Division did not take prompt or effective cancellation action in cases where it had reason to believe a registered product might be ineffective or potentially hazardous.

Although PRD has had specific cancellation authority for more than 5 years, it has *never* secured cancellation of a registration in a contested case.

The subcommittee investigation disclosed evidence of lengthy and unwarranted delays in initiating cancellation action after facts sufficient to justify such action became known to PRD.

Until a few weeks ago, PRD did not even have procedures for conducting hearings or studies which registrants may request as a matter of right before cancellation action can become effective. When

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registrants receiving cancellation notices requested hearings or studies, prosecution of the cancellation action was halted and the product left on the market.

A mistaken belief that positive evidence of hazard—rather than simply a lack of adequate assurance of safety—is necessary to support a cancellation action appears to have been a factor in

PRD's failure to initiate such action in cases where it was obviously justified.

Cancellation action against a number of products has been initiated during the subcommittee's investigation.

7. The Pesticides Regulation Division has consistently failed to take action to remove potentially hazardous products from marketing channels after cancellation of a pesticide registration or through suspension of a registration.

Although PRD has never secured cancellation of a registration in a contested case, there have been instances where registrations of potentially hazardous products have been canceled by consent or through failure of the registrant to contest the action. The subcommittee investigation disclosed that PRD has no procedures for taking action to remove such products from the market after cancellation of the registration or even for notifying the Enforcement Branch that the registration has been canceled.

PRD has no procedures or criteria for determining when a registration should be suspended on the ground that a product constitutes an "imminent hazard" to the public. Such action has been taken only once; but a product containing an identical amount of the same active ingredient was allowed to remain on the market without even bearing a required warning notice on its label.

In some cases, hazardous products were *deliberately* allowed to remain on the market after cancellation of registrations.

8. The Pesticides Regulation Division has no procedures for warning purchasers of potentially hazardous pesticide products.

Although removal of dangerous pesticides from marketing channels obviously does not protect buyers who already have the product in their homes, PRD has not procedures for issuing warning notices to the public when it becomes aware of possible hazards from particular pesticide products. By contrast, other units of the Agricultural Research Service apparently have procedures for warning against possible hazards to animals from regulated products which have already been sold.

PRD has recently issued warning notices concerning several pesticide products discussed during subcommittee hearings.

9. The Agricultural Research Service failed to take appropriate precautions against appointment of consultants to positions in which their duties might conflict with the financial interests of their private employer. Facts disclosed by the subcommittee investigation raised a number of serious conflict of interest questions.

Although Shell Chemical Co. is one of the country's largest producers of registered pesticide products, Dr. T. Roy Hansberry, an official of one of the company's affiliates, was appointed to a 1965 task force examining criteria used by PRD in determining whether pesticide registration applications should be approved. Before the appointment was made, an individual in the ARS Personnel Division

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(whom ARS officials report they have been unable to identify) certified on Dr. Hansberry's personnel clearance form that the agency did not know of any official business with his private employer which might constitute a conflict of interest.

Minutes kept by the task force's executive secretary are available for only one of its meetings; they indicate that he reminded the group of legal restrictions on disclosure of confidential information which should be kept in mind in view of Dr. Hansberry's association with a private firm. The executive secretary was subsequently dismissed by the task force chairman, and no further minutes were kept.

Dr. Mitchell R. Zavon, a medical consultant to Shell Chemical Co., served simultaneously as a consultant to the Pesticides Regulation Division. Documents examined by the subcommittee indicate that Dr. Zavon was actively concerned as a Shell consultant in scientific studies and in negotiations with Federal agencies relating to Shell's DDVP strip. The subcommittee investigation also disclosed that Dr. Zavon participated as a PRD consultant in a meeting at which safety questions relating to DDVP strips were discussed, but no action was recommended.

USDA records indicate that Dr. Zavon was originally appointed for the specific purpose of advising PRD on problems relating to Dieldrin, a pesticide produced by Shell Chemical Co. The subcommittee investigation did not disclose whether or not Dr. Zavon actually advised USDA, as a consultant, on any matter involving Dieldrin in which Shell had a financial interest.

Registration of Shell's DDVP strip was originally approved in 1963 after John S. Leary, Jr., then PRD's Chief Staff Officer for Pharmacology, overruled an objection raised by a subordinate. In November 1966, Mr. Leary gave notice that he was leaving PRD to accept employment with Shell Chemical Co. In December 1966, before leaving PDR, Mr. Leary recommended that PRD ignore a Public Health Service report opposing continued sale of DDVP strips. In 1968, as a Shell employee, Mr. Leary participated in a meeting at which Shell opposed addition of a warning notice to the label of its DDVP strip.

In view of the conflict of interest questions raised by the subcommittee investigation, the matters involving Dr. Hansberry, Dr. Zavon, and Mr. Leary have been or are being referred by USDA to the Department of Justice.

RECOMMENDATIONS

1. In view of the long-continued and serious deficiences which have been disclosed in administration of the Federal Insecticide, Fungicide, and Rodenticide Act by the USDA Pesticides Regulation Division, the committee recommends that the Secretary of Agriculture conduct a thorough review of PRD operations for the purpose of—

(a) Making certain that the administrative deficiencies discussed in this report (and any others found to exist) are promptly corrected;

(b) Insuring that the Pesticides Regulation Division is staffed by supervisory officials with sufficient qualifications, experience, and administrative ability to prevent any repetition of such deficiencies;

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(c) Taking any necessary steps to insure that there are adequate operating procedures and guidelines for all phases of PRD operations.

The committee further recommends that USDA officials at the highest levels and the General Accounting Office maintain close surveillance over future operations of the Pesticides Regulation Division.

It is the committee's understanding that action has been or is being taken to correct at least some of the deficiencies described in this report, and that the USDA Office of Inspector General is examining some phases of PRD operations at the present time.

Committee recommendations concerning specific aspects of USDA operations follow.

2. The committee recommends that USDA take prompt action to make certain that pesticide products are not registered or reregistered unless there is adequate assurance that they are safe and effective.

The committee particularly recommends that such steps as are necessary be taken to insure effective and unreserved cooperation by the Pesticides Regulation Division with the Department of Health, Education, and Welfare and other agencies concerned with the safety and effectiveness of pesticide products. Immediate action should be taken to make certain that unresolved safety questions raised by HEW or the Department of Interior concerning products proposed for registration are referred to the Secretary of Agriculture, and that the provision of the interdepartmental agreement referring to furnishing of scientific evidence not be misconstrued as in any way shifting the burden of proof of safety away from the would-be registrant. Appropriate steps should be taken to insure that any proposed pesticide uses which may result in residues on food are reviewed by the Food and Drug Administration.

Policies and procedures with respect to label review should be strengthened, with a view to obtaining the maximum practicable assurance that all labels approved in the future contain directions for use which incorporate all necessary warning statements, use format and language which will be as clearly readable and understandable as possible, and do not contain misleading effectiveness claims.

Any necessary action should be taken to make certain that all USDA personnel concerned with pesticide registration activities fully understand that the safety of a pesticide product must be established before it can be registered and that the burden of proving a product's safety rests with the would-be registrant.

3. The committee recommends that the pesticides regulation division review, as soon as feasible, all current pesticide registrations in order to identify and take appropriate action with respect to any registered products which—

(a) Bear inadequate, misleading, contradictory or confusing labeling;

(b) Were approved without resolution of safety questions raised by HEW;

(c) Make unjustified effectiveness claims;

(d) Are approved for uses likely to result in adulteration or contamination of food.

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4. The Committee recommends that USDA take prompt action to improve its present arrangements for obtaining data concerning pesticide poisonings.

The committee specifically recommends that USDA take steps to obtain and analyze, on a current basis, all useful information on pesticide poisonings reasonably available from HEW poison control centers and other Government agencies. The committee further recommends that USDA work with other Government agencies toward improving the amount and usefulness of pesticide poisoning data available.

5. The committee recommends that USDA take appropriate

steps to insure that cancellation proceedings are promptly initiated whenever a reasonable question as to the safety of a registered product becomes apparent.

The committee further recommends that USDA provide such additional legal and other assistance to the Pesticides Regulation Division as may be necessary to handle the present backlog of cancellation cases and to insure that PRD's recently adopted rules and procedures for cancellation actions are adequate.

6. The committee recommends that USDA take necessary action to provide better protection for the public against potentially hazardous pesticides in marketing channels.

The committee specifically recommends that appropriate criteria for determining when to suspend a product registration to prevent "imminent hazard" to the public be established without delay and that adequate procedures to insure uniform application of such criteria be adopted.

The committee further recommends that procedures be established to insure that the PRD enforcement branch is notified of cancellations of registrations and that immediate action is taken to remove potentially hazardous products from marketing channels when registrations are cancelled. In particular, it recommends that the Secretary take whatever action may be necessary to provide positive assurance that officials of the Pesticides Regulation Division do not deliberately allow illegal and potentially hazardous products to remain on the market in the future.

In addition, the committee recommends that USDA establish procedures for issuance of warning notices to purchasers when it receives information indicating that a pesticide product may be potentially hazardous to users.

7. The committee recommends that USDA take such action as may be necessary to insure that individuals are not appointed to serve as employees of the Department under circumstances in which their personal financial interests or those of their private employer may conflict with their official duties. The committee further recommends that added precautions be taken to prevent violation of conflict of interest laws or regulations by employees or former employees.

The committee specifically recommends that USDA strengthen its procedures for clearing special Government employees from a conflict of interest standpoint. Responsibility for clearing each such appointment should be assigned to a specific individual whose identity is made a matter of record. In addition to being familiar with Federal conflict of interest laws and regulations, individuals authorized to grant clearances should also have full knowledge of the governmental [p. 19] duties and private financial interests involved. If it appears that a possible conflict of interest is involved, the appointment should not be made; if exceptional circumstances are deemed to justify an exception, legal requirements for exempting an employee from the conflict of interest laws should be carefully observed.

The committee further recommends and specifically requests that USDA make a detailed and searching investigation of the circumstances involved in appointment of Dr. Hansberry to the 1965 task force, including the name(s) of the person or persons responsible for clearing the appointment, and make a full report to the committee on its findings. In addition, the committee recommends that USDA review the duties and financial interests of all individuals now on its rolls as special Government employees to determine whether any actual or potential conflicts of interest exist.

In instances where USDA employees, including special Government employees, have financial interests in organizations doing business with USDA, the committee recommends that the persons responsible for supervising their work be informed of such interests and instructed to avoid assigning such employees to any duties which could result in or give the appearance of creating a conflict of interest. USDA officials should be specifically warned against permitting former employees to represent private firms in connection with matters in which such former employees participated personally and substantially as USDA employees. USDA officials should also be instructed to carefully screen work assignments of employees who have accepted or are negotiating for employment with outside organizations to avoid possible conflicts of interest.

When matters relating to pesticide registrations or cancellations are referred to advisory committees appointed by the National Academy of Sciences, the committee recommends that USDA take appropriate action to insure that members of such committees meet the same standards with respect to conflicts of interest as would be required of Federal employees.

The committee further recommends that USDA take adequate precautions to insure that adequate records, including minutes of meetings, are kept concerning the work of advisory groups whose members are not all full-time Government employees.

8. The committee recommends that USDA take appropriate action to provide additional personnel for the prosecutions and imports section of the Pesticides Regulation Division's Enforcement Branch.

BACKGROUND

FEDERAL REGULATION OF PESTICIDES

Background

Since 1947, the Federal Insecticide, Fungicide, and Rodenticide Act[1] (FIFRA) has provided for regulation of marketing of pesticides in interstate commerce. The act requires that all pesticides must be registered with the Department of Agriculture before they can be shipped in interstate commerce. Before a pesticide can be registered, evidence must be presented to show that it is safe and effective when used as directed. Responsibility for administering the provisions of the act has been assigned by the Department of Agriculture to the

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Pesticides Regulation Division (PRD), a unit of the Agricultural Research Services (ARS).

Certain provisions of the Federal Food, Drug, and Cosmetic Act,[2] after which FIFRA is patterned, also directly affect the regulation of pesticides. This act is administered by the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW).

Pesticides or "economic poisons" covered by FIFRA include all substances or mixtures of substances intended for—

> * * * preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals * * *

As defined in the act, as amended, the term "economic poison" also includes any substances intended for use as plant regulators, defoliants or dessicants.

According to USDA, more than 45,000 products made from one or more of some 900 chemical compounds are currently registered under the act. These include not only products used to combat weeds, insects, rodents and plant diseases, both on the farm and around the home, but chemicals used for sterilizing and disinfecting surgical instruments and restaurant equipment. Sales of registered pesticides are estimated at more than a billion dollars annually. Approximately half the registered pesticides are designed for nonfarm uses, although those sold for agricultural use account for the largest sales volume. The Department of Agriculture regards agricultural pesticides as so important that it has estimated crop and livestock production would drop 25 to 30 percent if no pesticides were used.

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[1] 7 U.S.C. 135-135k, hearing, record, appendix, p.248.

[2] 21 U.S.C. 301.

Statutory authority for pesticides regulation

The basic purpose of FIFRA is to insure that pesticides shipped and held for sale in interstate commerce are safe and effective. The act authorizes and directs the Department of Agriculture to refuse to register a product if it does not appear to warrant the claims made for it. The act prohibits interstate shipment of pesticides which are not registered. It also prohibits interstate shipment of a registered pesticide if any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration. In addition, the act prohibits interstate shipment of a pesticide if the composition differs from its composition as represented in connection with its registration.

Economic poisons which contain any substance in quantities highly toxic to man cannot legally be shipped in interstate commerce unless the label bears the skull and crossbones, the word "Poison" in red on a background of a distinctly contrasting color, and a statement of the antidote for the poison.

The act further prohibits the interstate shipment of pesticides which are adulterated or misbranded. Under the act, an economic poison is "misbranded" if its labeling bears any statement relative to it or its ingredients which is false or misleading in any particular; if it is an imitation of or offered for sale under the name of another economic poison; or if its labeling does not contain directions for use and warning or caution statements adequate if complied with to prevent injury and protect the public. A pesticide is also misbranded under the act if

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any required statement is not prominently displayed on its labeling in such terms as to be read and understood by the ordinary individual under customary conditions of purchase and use; or if it is injurious to living man or other vertebrate animals when used as directed or in accordance with commonly recognized practice.

The registration of any economic poison may be canceled at the end of 5 years, and at the end of each additional 5-year period thereafter, unless the registrant requests that it be continued. A registration may be canceled at any time if it does not appear that the product or its labeling complies with the provisions of the act; the cancellation must be carried out in accordance with procedures specified in the act and becomes effective, if not contested, 30 days after notice. The registration on an economic poison may be suspended immediately when the Secretary finds that such action is necessary to prevent an imminent hazard to the public. The registrant must then be given an opportunity to oppose the suspension, but the product cannot legally be sold until the matter is resolved.

Economic poisons imported into the United States are subject to the provisions of FIFRA. However, products intended solely for export and prepared or packed according to the specifications or direction of the foreign purchaser are not subject to the act.

Any person violating provisions of the act may be fined for his first offense and fined, imprisoned (for not more than 1 year) or both for each subsequent offense occurring not more than 5 years after the last previous conviction. If criminal prosecution is contemplated because it appears from an examination of an economic poison that the product does not comply with the requirements of the act, notice and an opportunity to present his views must first be given to the person against whom such prosecution is contemplated.

The Department of Agriculture is authorized by the act to institute court proceedings for seizure and appropriate disposition of economic poisons in interstate commerce which are adulterated, misbranded or unregistered. Manufacturers, distributors, carriers, and sellers of economic poisons subject to the act are required to allow access to shipment records to authorized personnel of the Department of Agriculture, although specific evidence obtained in this manner may not be used in a criminal prosecution against the person from whom obtained.

The Department of Agriculture is not required to initiate criminal prosecutions or seizure proceedings for minor violations of the act when it believes the public interest will be adequately served by a suitable written notice of warning. The act requires the Department to publish notices of all judgments in actions instituted under its authority.

While FIFRA covers only economic poisons in interstate commerce, almost all States have generally similar registration laws applicable to pesticides distributed within the State.

The pesticide chemical and food additive amendments to the Federal Food, Drug, and Cosmetic Act provide that a tolerance must be established by the Food and Drug Administration in the event a registered use of an economic poison will result in residues on or in food and feedstuffs.

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ARS PESTICIDES REGULATION DIVISION

Organization of Pesticides Regulation Division

The Agricultural Research Service was established in 1953 to consolidate most of the physical, biological, chemical, and engineering research carried out by the Department of Agriculture within a single organization. Agricultural Research Service also is responsible for a number of regulatory programs, including pesticides regulation. Pesticides regulation activities are assigned to the Pesticides Regulation Division.

According to an organization chart supplied by PRD,[3] Division personnel are assigned to two branches—one for registration and one for enforcement—and five separate staffs performing specialized functions.

The registration branch handles administrative details, correspondence and records relating to registration applications and cancellation proceedings. Product evaluation staffs are responsible for making final decisions, within the guidelines of division policy and criteria, concerning approval of applications or cancellation of registrations. Separate product evaluation staffs are established to deal with disinfectants, fungicides, insecticides, herbicides, and plant growth regulators, and rodenticides.

The enforcement branch is responsible for planning, directing, and coordinating with other Federal and State programs the field activities necessary to effectively regulate the marketing of pesticides. These include accident investigations, inspection and sampling of products in marketing channels, laboratory analysis of product samples, seizure and recall action, and preparing information necessary to initiate criminal prosecutions.

The other four staff groups whose responsibilities are described in the organization charts are the regulation and interpretation staff, the interagency coordination staff, the new chemicals evaluation staff, and the pesticides safety advisory staff.

Registration procedures and operations

The following description of registration procedures used by the Pesticides Regulation Division was supplied by PRD:[4]

> Before a product can be registered, the manufacturer or formulator must file a formal application, submit five copies of the proposed labeling, a statement of complete chemical composition of the product, and extensive data on both efficacy and safety.

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[3] Hearing record, p. 297.

[4] Hearing record, p. 241.

The new chemicals evaluation staff first reviews the label for accuracy of chemical composition, ingredient statement, net contents, chemical nomenclature, and product name.

The product evaluation staff, made up of specialists in entomology, plant pathology, agronomy, bacteriology, and animal biology, reviews the labels and data for effectiveness. Among the criteria used are the pests to be controlled, dosage and rate of application, soil persistence, metabolism, phytotoxicity, migration, translocation, and method of application. [p. 23]

The pesticides safety evaluation staff reviews the toxicological data with respect to safety to man, fish, and wildlife, and other beneficial animals. The principal criteria used in the safety evaluation are the results of acute oral, dermal, and inhalation studies, subacute feeding studies, eye and skin irritation, sensitization, neurotoxicity, reproduction, and carcinogenic studies. On the basis of the data, it can be determined whether the front panel of the label shall carry the signal word "Danger," "Warning," or "Caution," and what precautionary statements are necessary, which, if complied with, are adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals.

If the product is to be used on food or feed, careful consideration is given to residues that are likely to occur from such use and in which case the matter is referred to the Food and Drug Administration for establishing a tolerance. After the scientific review has been completed, the application is again reviewed in its entirety to determine if the product is acceptable for registration. If data are inadequate, the applicant is so advised and registration is withheld until all requirements have been satisfied. If it appears that registration is in order, the label and data are referred to the Department of the Interior and/or the Department of Health, Education, and Welfare as provided for under the interdepartmental agreement. The purpose of this agreement is to give the other departments an opportunity to advise the Department of Agriculture of any changes in labeling that might be necessary to further protect the public, or to protect fish and wildlife. Our scientists are in day-to-day communication with HEW and Interior.

During fiscal year 1968, according to its records, the Pesticides Regulation Division accepted nearly 5,000 new products for registration and processed almost 11,000 amendments to labels of previously registered products. (Labels of registered products are amended because of new patterns of use or minor changes in formulation or precautionary statements.) During the same period, about 10,000 pesticide labels were reviewed by the Public Health Service (PHS) and around 4,500 by the Department of the Interior. All labels for new products were referred to PHS for review; however, amendments to labels were not usually so referred if no safety question was believed to be involved.

The Department of Interior reviewed labels for pesticide uses which might affect birds, animals, and fish and their habitats, but did not review those involving only household uses.

As of mid-1969, about 105 employees of the Pesticides Regulation Division were assigned to duties relating to the registration of pesticide products. About 60 of these worked directly under the Office of the Director or were assigned to product evaluation staffs, with the remainder working in the registration branch.

Enforcement procedures and operations

The basic objective of Pesticides Regulation Division enforcement activities is to insure that pesticide products being marketed in interstate commerce meet the standards required for registration and sale.

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For this purpose, PRD inspectors inspect and sample pesticides in warehouses and sales outlets throughout the United States. Pesticide labels are examined to ascertain whether the product is registered and whether the information contained on the label is adequate. Samples of pesticides are sent to PRD laboratories for analysis to determine whether the product contains all ingredients listed on the label in the amounts listed and whether or not the product is adulterated with chemicals or other materials not listed on the label. Results of laboratory analysis of samples are forwarded to Washington, where Enforcement Branch personnel determine what further action should be taken with respect to those results indicating violations.

As of mid-1969, the PRD Enforcement Branch had 5 supervisory inspectors and 26 field inspectors stationed at about 20 locations throughout the United States.

The Pesticides Regulation Division has five chemistry laboratories staffed by a total of five supervisory chemists and 27 other chemists, as well as nontechnical personnel. These laboratories analyze samples to determine their composition and the presence of adulterants. In addition, PRD has seven laboratories which perform biological testing related to safety and effectiveness. These consist of two plant biology laboratories, two entomology laboratories, a pharmacological laboratory, an animal biology laboratory and a bacteriological laboratory. These are staffed by seven supervisors and 17 other professionals. During fiscal year 1968, the chemistry laboratories tested 5,219 samples and the biological laboratories tested 2,737.

The Pesticides Regulation Division has cooperative agreements with about half the States and informal working arrangements with a number of cities. Under the cooperative agreements, State inspectors can, upon request, collect samples, obtain records of interstate shipment, and ship samples to Federal laboratories.

ENFORCEMENT ACTIVITIES

Failure to remove illegal products from market

On September 10, 1968, the Comptroller General issued a report to the Congress on "Need to Improve Regulatory Enforcement Procedures Involving Pesticides."[8] The report was based on a review by General Accounting Office personnel of enforcement actions initiated by the Pesticides Regulation Division during fiscal year 1966 and related events occurring before and after this period. The report clearly showed that PRD procedures for removal from the market of hazardous or ineffective pesticide products being sold illegally were, as of mid-1967, almost totally inadequate.

The GAO report did not criticize the manner in which samples of pesticide products were collected and analyzed to determine whether the products complied with provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. According to the report, PRD tested and reviewed 2,751 samples of pesticide products in fiscal year 1966. Of these, 750 were found to be in violation of the act; 188 of the 750 violations were determined by PRD to be minor, requiring only a written notice of warning to the registrant rather than seizure or criminal pros- [p. 25] ecution. The other 562 samples—about 20 percent of all those tested and reviewed—were considered to be in major violation of the act.

Although the act authorizes PRD to obtain information concerning the location of pesticide products from the shipping records of manufacturers, distributors, carriers and dealers, the GAO review showed that PRD did not have procedures or standards for obtaining such information. GAO found that generally it was PRD practice to remove from the market only the amount of product, if any, found at the one retail or wholesale outlet where the sample was collected, without any attempt to determine whether additional quantities of the violative products were in marketing channels at other locations. According to the report, 106 seizure actions were taken in fiscal year 1966; however, 22 of these did not result in removal of any quantity of pesticide products from the market because the product was no longer on the shelves at the location where the sample had been taken. The other 84 seizure actions, involving 79 different products, affected only 80 different wholesale or retail outlets.

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[8] Hearing record, appendix, p. 141.

The GAO report cited a graphic example of failure by PRD to effectively remove a dangerous illegal product from the market. According to the report, registrations of 58 products containing the chemical thallium were canceled as of the end of August 1965. The cancellations took place because the use of thallium for the control of insects and rodents had resulted in a large number of poisonings; statistics of the Public Health Service indicated that there were about 400 reported cases of thallium poisoning of children in 1962 and 1963. Despite the cancellations, the report disclosed, products containing thallium were found in six of 22 retail establishments visited in the Washington area in late 1967 —more than 2 years later.

The GAO findings concerning removal of illegal products from the market contrasted sharply with a claim by the Department of Agriculture that—

> Aggressive enforcement action to take * * * dangerous pesticides off the market has been a significant part of the protection being given the public * * *.[6]

Thirteen-year failure to prosecute

In addition to criticizing PRD procedures for removing illegal pesticide products from the market, the September 1968 GAO report also criticized the Pesticides Regulation Division for failing to take effective action to initiate prosecution of those responsible for placing the illegal products on the market.

According to the report, during the fiscal year 1966 PRD notified 242 shippers of pesticide products that criminal proceedings were contemplated against them. The notifications were based on 456 samples of pesticide products considered by PRD to be in major violation of the Federal Insecticide, Fungicide, and Rodenticide Act, each of which was regarded as evidencing a separate violation of the act. One hundred sixty-five of the 242 shippers were responsible for only a single violative sample; the other 77 had shipped a total of 291. One hundred thirty-four violative samples—nearly 30 percent of the total—were shipped by 17 firms, each of which had shipped five or more. Two firms were responsible for 20 violative samples each.

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[6] The Yearbook of Agriculture, 1966, p. 279.

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The General Accounting Office found, in its report, that PRD did not have established procedures for determining under what circumstances evidence of violations of the act would be reported to the Department of Justice for prosecution. The GAO also found that, despite evidence of repeated violations by some shippers, not a single case of alleged violations of the act was reported to the Department of Justice for prosecution during the 13-year period from February 1955 through February 1968. The report further noted that the complete absence of prosecutions occurred despite the fact that some shippers simply ignored notices of contemplated proceedings and made no attempt to explain apparent serious violations disclosed by samples.

Failure to publish notices of judgments

Section 6(e) of the Federal Insecticide, Fungicide, and Rodenticide Act requires that the Secretary of Agriculture give notice by publication of all judgments entered in actions instituted under the authority of the Act. The GAO found that, from the inception of FIFRA in 1947 to November 1964, 18 publications summarizing the results of 515 judgments (primarily seizures) had been issued at intervals averaging about 6 months. However, the GAO found, no publications had been issued from November 1964 through December 1967. During this period, the report stated, there was an accumulation of about 250 judgments which had not been published. The explanation offered for USDA's failure to publish notices of these judgments, according to the report, was that the employee assigned to compiling the information necessary for publishing the notices had retired and had not been replaced.

Testimony concerning GAO findings

During subcommittee hearings, Department of Agriculture witnesses were asked whether they found any fault with the September 1968 GAO report and a subsequent report issued in February 1969. Dr. Robert J. Anderson, Associate Administrator of the Agricultural Research Service, gave the following responses:[7]

> No, sir. On the contrary, we found these reports to be very helpful to us in carrying out our responsibility in administering the act.

USDA witnesses specifically confirmed GAO findings concerning the lack of procedures for prosecution of violations of the act and the failure of PRD to refer a single case to the Department of Justice for prosecution over a 13-year period. They further acknowledged that no notices of judgment had been issued during a period of more than 4 years.[8]

Testimony at subcommittee hearings also supported GAO criticism of PRD's failure to remove illegal pesticide products from the market. Dr. Anderson admitted that, as of the end of 1966, PRD policy was to seize only the quantity of illegal pesticide products found at the location where the sample was taken; there were no procedures for records examinations to locate additional quantities of illegal products or multiple seizures to remove them from distribution channels.[9]

Subcommittee hearings also established that existing stocks of rat poison containing thallium had deliberately been left on the market

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after registrations for such use had been cancelled because of the large number of injuries and deaths—mostly involving children—caused by thallium. PRD took action in June 1960 to limit the amount of thallium which could be used in an attempt to reduce the possibility of fatal accidents involving such products; however, deaths continued to occur. All registrations for thallium products were finally cancelled effective August 31, 1965, but the Department of Agriculture knowingly allowed continued sale of products already on the market. Dr. Harry W. Hays, Director of the Pesticides Regulation Division, stated that:[10]

> We did not make any attempt to withdraw the materials from the market on the premise * * * that the cancellation would in itself prevent the continued proliferation and thus a phasing out, a dilution and finally disappearance.

Dr. Hays was unable to tell the subcommittee how many deaths had resulted from thallium or how many accident reports involving thallium had been received after 1963.

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[7] Hearing record, p. 6.
[8] Hearing record, pp. 33-35.
[9] Hearing record, p. 15.
[10] Hearing record, p. 17.

Dr. Anderson told the subcommittee that the Department of Agriculture believed voluntary recalls by the manufacturer are "* * * the most effective and efficient * * *" means for removing violative products from the market. Questioning of USDA witnesses established that no use of voluntary recalls had been made from the enactment of FIFRA in 1947 until September 1967, a situation Dr. Anderson attributed at first to "* * * lack of authority in the act providing for the recall action." Under further questioning, Dr. Anderson confirmed that voluntary recall procedures—which he described as "working quite well"—had been instituted without necessity for enactment of any additional legal authority.[11]

Improvement in enforcement procedures and operations

Significant improvements in PRD enforcement procedures and operations were made after the appointment in mid-1967 of an assistant director for enforcement, Lowell E. Miller.

In September 1967 according to testimony at subcommittee hearings, PRD made its first request that a manufacturer voluntarily withdraw a violative product from the market. From July 1, 1968, through April 30, 1969, 32 such requests for voluntary recalls were made. In a May 22, 1968, letter to the General Accounting Office, the acting administrator of the Agricultural Research Service stated that ARS would examine shipping records to obtain product location data and make multiple seizures in instances where manufacturers refused to recall violative products from the market voluntarily. Formal recall procedures were approved on May 5, two days before the subcommittee's first hearing.[12]

In December 1967, a new Prosecution and Import Section was created. The stated purpose of this section is—

> * * * not only to establish more effective procedures for the handling of prosecution but also to focus attention upon the fact that prosecutions are an important part of the enforcement program.

Operating guidelines for determining under what circumstances cases would be forwarded to the Department of Justice for prosecution,

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which had not previously existed, were established in early 1968.

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[11] Hearing record, pp. 3, 7.
[12] Hearing record, pp. 3, 6, 178.

The guidelines call for cases to be forwarded for prosecution where—

> * * * (1) the evidence indicates that the violation was willful, (2) the violation is of a serious nature (e.g., significant deficiency of active ingredient or contamination) and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.[13]

Agricultural Research Service told the subcommittee that it was now "* * * putting major emphasis on starting action against repeat violators." The agency reported that the first criminal indictment in at least 13 years alleging violation of the Federal Insecticide, Fungicide, and Rodenticide Act had been returned by a grand jury in Chicago in March 1969. Agricultural Research Service further reported that two additional case files had been forwarded to USDA's Office of General Counsel with a recommendation for prosecution and that case files relating to alleged violations of the act by approximately 20 companies were in various stages of preparation.[14]

The subcommittee was assured that steps had been taken to resume publication of notices of judgment and to provide for regular publication of such notices in the future.[15]

Serious deficiencies remaining

Although subcommittee hearings indicated that significant progress had been made in improving Enforcement Branch procedures and operations, they also disclosed that serious deficiencies remained.

In a May 22, 1968, letter to the General Accounting Office, Dr. R. J. Anderson, acting administrator of the Agricultural Research Service, stated that ARS agreed with GAO's belief that prosecutions were necessary for a strong enforcement program. Dr. Anderson further advised the General Accounting Office with respect to the newly created prosecutions and imports section that: [16]

> This section became sufficiently staffed in January 1968 so that work could be commenced on setting up procedures for the handling of prosecutions. We are currently reviewing all cases in the recent past to determine whether criminal prosecution should be recommended.

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[13] Hearing record, p. 4.
[14] Hearing record, p. 4.
[15] Hearing record, p. 35.
[16] Hearing record, p. 177.

Testimony at a subcommittee hearing on May 7, 1969, disclosed that the entire staff of the prosecutions and import section consisted of one man at the professional level and one clerical assistant. In addition to reviewing cases for possible prosecution, the one professional also had responsibility for supervising all imports of pesticides. The backlog of cases being reviewed for prosecution was estimated at about 20, and PRD witnesses admitted that more than 20 additional cases might be added to the backlog before the current 20 had been reviewed.[17]

Subcommittee hearings also disclosed that there were no procedures for warning the general public about possible danger when potentially hazardous pesticides were found in marketing channels. In addition, while procedures for removing dangerous products located by PRD inspectors appeared to be adequate, it was found that there were no

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procedures to insure that appropriate enforcement action was taken after a registration was canceled because of a safety question or lack of effectiveness. These matters are discussed in greater detail in this report.

REGISTRATION ACTIVITIES

LINDANE

Failure to resolve safety questions relating to lindane

The September 1968 GAO report on enforcement procedures, which led to the subcommittee investigation, was followed by a second report on "Need to Resolve Questions of Safety Involving Certain Registered Uses of Lindane Pesticide Pellets." [18] This report was issued on February 20, 1969, after the subcommittee investigation had been initiated.

In its report, the General Accounting Office found that the ARS Pesticides Regulation Division had continued to register pellets containing the chemical lindane for use in continuous vaporizing devices in commercial and industrial establishments—such as restaurants and other food handling businesses—even though the Public Health Service and other Federal, State, and private organizations had opposed this use over a long period of time.

According to the report, the initial registration of lindane pellets for use in continuously operating vaporizing devices in commercial and industrial establishments took place in 1950 or 1951 without objection from the Public Health Service or the Food and Drug Administration. In October 1952, the Interdepartmental Committee on Pest Control, composed of representatives of the Departments of Agriculture, Interior and Defense and the Federal Security Agency (predecessor to the Department of Health, Education, and Welfare), recommended against the use of insecticide vaporizers in rooms or areas where food is served, processed or stored unless it could be demonstrated that contamination of food did not occur. Thereafter, the report indicated, at least 14 States and 35 municipalities adopted measures to control the installation, sale or use of lindane vaporizers.

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[17] Hearing record, p. 34.

[18] Hearing record, appendix, p. 181.

In 1953, according to the report, a copy of a letter from the Secretary of Health, Education, and Welfare raising questions concerning possible health hazards associated with the use of lindane vaporizers was transmitted to ARS. Also in 1953, a study by the Food and Drug Administration concluded that use of lindane vaporizers around food resulted in contamination. The study further concluded that food would not be protected from such contamination by the use of common wrapping or covering materials, except metal.

In spite of the questions raised concerning lindane, PRD continued to register and reregister lindane pellets for use in continuous vaporizing devices. By contrast, the unit of the Department of Agriculture responsible for meat inspection—which was also a part of the Agricultural Research Service at the time—refused to permit the use of lindane vaporizers in meat processing and slaughtering establishments.

In early 1964, an interdepartmental agreement intended to coordinate activities relating to pesticides registration was signed by the Secretaries of Agriculture, Interior, and Health, Education, and Welfare. Under the agreement, proposed registrations and reregistrations

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of pesticides were to be submitted by the Department of Agriculture to HEW for review. The Public Health Service, which reviewed proposed registrations for HEW from the standpoint of safety, thereafter objected to registration of lindane pellets for use in continuous vaporizers in food handling establishments. In 1965, an ad hoc committee was appointed by the Bureau of State Services, PHS, to review the use of pesticide vaporizing devices. The committee's report, which expressed unanimous opposition to the use of lindane vaporizers, was transmitted to ARS in September 1966.

In July 1967, according to the GAO report, a PRD inspector called attention to what he regarded as contradictory labeling of lindane pellets, pointing out that one side of the label called for use in restaurants, bars, and offices, while the other side warned against inhalation and against contamination of food. The inspector was informed that the labeling he was questioning was substantially the same as that accepted for registration; apparently no further action was taken.

Although the question of safety of lindane vaporizers had been raised repeatedly, the General Accounting Office found that the Pesticides Regulations Division had taken no action to resolve it. The GAO report also noted that PRD apparently was acting on the assumption that once a pesticide had been registered the burden of proof was on PRD to establish that is was unsafe before reregistration could be denied.

Belated action to stop sale of lindane

On November 27, 1968, after reviewing a draft of the GAO report relating to lindane, the Department of Agriculture wrote the General Accounting Office that:[19]

> Information has recently come to our attention which indicates the need for a reevaluation of the safety of lindane in an uncontrolled environment. It has been shown that malnutrition greatly enhances the toxicity of lindane in laboratory animals. Significant residue levels have also been found in tissues of animals exposed to vaporized lindane. * * *

USDA advised GAO that ARS was arranging a meeting with departmental representatives responsible for carrying out provisions of the 1964 Interagency Agreement to determine what steps should be taken concerning the problem of lindane vaporizers. USDA further advised GAO that a meeting was being scheduled with medical experts who provide advice and counsel to the Pesticides Regulation Division on matters relating to the use of pesticides.

On April 29, 1969, some 2 months after public release of the GAO report, USDA announced that it was initiating action to cancel registrations of lindane products for use in vaporizing devices "because of undue risk to the health of persons chronically exposed to the vapors." The USDA announcement further stated that the "expansion of scientific knowledge since 1951" had also raised serious doubts about the safe use of lindane in areas where food is being processed or stored. According to the announcement, studies initiated several months before and intensified after publication of the GAO report had disclosed that practically all food, whether packaged or unpackaged, contained [p. 31] illegal residues after 5 days exposure to lindane under simulated restaurant conditions.

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[19] Hearing record, p. 216.

Questionable excuses and misleading statements

In testimony before the subcommittee, ARS witnesses admitted that the agency first became aware of objections by the Public Health Service and the Food and Drug Administration to the use of lindane vaporizers in 1953. However, they contended that the agency's failure to act for some 16 years was necessitated by its lack of scientific data establishing that such use of lindane was hazardous. ARS witnesses also claimed that they had looked everywhere for such data, but had been unable to find it.[20]

USDA witnesses acknowledged in their testimony that, under the law, the burden of establishing that a pesticide chemical is safe rests upon the registrant. However, their testimony indicated that when PRD was warned of possible health hazards associated with use of lindane vaporizers, it disregarded this fact. It further indicated that instead of calling upon the registrants to submit additional evidence of safety, PRD acted as though it was the responsibility of the Public Health Service to provide scientific data proving that use of lindane vaporizers was dangerous before any action could or should be taken.[21]

Testimony of ARS officials suggested that the agency had made vigorous efforts over a long period of time to obtain information which might resolve questions concerning the safety of lindane vaporizers. The record does not support this contention. ARS did not bother to conduct laboratory tests (or require that such tests be conducted by registrants) for almost 16 years after questions about lindane were raised by other Federal agencies. When such tests finally were performed in February 1969, it took only 5 days to establish that use of lindane vaporizers under simulated restaurant conditions would result in illegal residues on food.

The subcommittee investigation further disclosed that a copy of a 1953 Food and Drug Administration study, which concluded that the use of lindane vaporizers around food would result in contamination, had been provided to ARS not long after it was completed.

In its November 27, 1968, letter to the General Accounting

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[20] Hearing record, pp. 24–25, 29.

[21] Hearing record, pp. 24–29, 67.

Office, the Department of Agriculture indicated that ARS was arranging a meeting concerning the lindane problem with medical consultants and with departmental representatives responsible for carrying out the interagency agreement on pesticides. USDA further indicated that the meetings were being scheduled because of information which had recently come to its attention relating to residue levels in tissues of animals exposed to vaporized lindane and to the effect of malnutrition on the toxicity of lindane in laboratory animals. At subcommittee hearings, ARS witnesses presented testimony apparently intended to imply that the recently obtained information formed the primary basis for a conclusion by its medical advisers that use of lindane vaporizers constituted an undue risk to the health of those continuously exposed to the vapors.[22] Further inquiry by the subcommittee disclosed however, that the report prepared by the medical advisory panel did not even mention the recently obtained information purportedly responsible for their consideration of the lindane problem. Instead, the

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panel's report emphasized 1965 and 1967 articles describing a possible relationship between the use of vaporized lindane and the development of aplastic anemia in humans. An advance copy of the 1967 article had been sent to and received by Harry W. Hays, Director of the Pesticides Regulation Division, in February 1967.

The subcommittee investigation also disclosed that the lindane problem had first been referred to PRD's medical advisory panel in October 1966, more than 2 years before the November 1968 letter to GAO. In addition, the subcommittee found that the meeting of departmental representatives referred to in the letter did not take place until March 19, 1969, and that minutes of this meeting do not disclose any reference whatever to lindane.

CLAIMED IMPROVEMENT

In testimony before the subcommittee, witnesses from the Agricultural Research Service acknowledged the existence of deficiencies in registration procedures in past years. However, they contended that significant improvements had been made, attributing much of the progress claimed to the work of a 1965 task force on the pesticide regulation and the subsequent hiring of the task force chairman, Dr. Harry W. Hays, as Director of the Pesticides Regulation Division. Before joining PRD in mid-1966, Dr. Hays had served for almost 10 years as Director of the Advisory Center on Toxicology of the National Academy of Sciences-National Research Council.

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[22] Hearing records, pp. 5, 216-217.

Dr. George W. Irving, Administrator of ARS, described the work of the task force in his testimony and stated that:[23]

> We are now in vastly better condition with respect to registration than we were prior to that time.

Dr. Robert J. Anderson, ARS's Associate Administrator, indicated in his testimony that the appointment of the task force by the Secretary of Agriculture marked the beginning of efforts to strengthen administration of the Federal Insecticide, Fungicide, and Rodenticide Act. Dr. Anderson told the subcommittee that, after Dr. Hays became Director of PRD:[24]

> We reorganized the Division, giving greater emphasis to criteria of safety used in the registration process.

The report of the task force appears on pages 248–296 of the hearing record. A statement concerning recommendations of the task force and action taken to carry them out appears in the hearing record on pages 48–50.

INTERAGENCY COOPERATION

Interdepartmental agreement on coordination of activities

Under the Federal Insecticide, Fungicide, and Rodenticide Act, basic responsibility for registration of pesticides is placed in the Department of Agriculture. However, other Federal agencies have significant responsibilities and interests involving registration of pesticides. The Food and Drug Administration is required, under the Federal Food, Drug, and Cosmetic Act, to establish a safe tolerance before pesticides can legally be registered for uses which will result in residues on or in food or feedstuffs. The Public Health Service is concerned about

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the effect of pesticides on human health. The Department of the Interior administers programs designed to protect fish and wildlife from pesticide contamination.

In its May 15, 1963, Report on Use of Pesticides, the President's Science Advisory Committee recommended, among other things, that:

> The Secretaries of Agriculture, Interior, and Health, Education, and Welfare review and define their roles in the regis-

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[23] Hearing record, p. 52.

[24] Hearing record, p. 14.

tration of pesticides that are not present on food, but that may impinge on fish and wildlife or come into intimate contact with the public.

In response to the report of the President's Committee, the Secretaries of the three departments signed a memorandum of agreement for the stated purpose of "Coordination of activities of the three departments pertaining to pesticides with special reference to registration and the setting of tolerances * * *." The first signature was affixed to the agreement on March 27, 1964; the last one on April 8, 1964. (The full text of the agreement appears in the hearing record on pp. 70–71.)

The agreement described the existing responsibilities of each department as follows:

Department of the Interior

Fish and Wildlife Service.—Conserving beneficial wild birds, mammals, fish, and their food organisms and habitat, with regard to pesticides.

Department of Health, Education, and Welfare

U.S. Public Health Service.—Protecting and improving the health of man in regard to pesticides.

Food and Drug Administration.—Establishing tolerances for pesticides in or on raw agricultural commodities and processed foods.

Department of Agriculture

Agricultural Research Service.—Providing for the safe and effective use of pesticides, including the registration thereof.

The agreement provides for each of the three departments to keep the others fully informed of knowledge about pesticides which comes into its possession. It specifies that USDA is to furnish the other departments with a weekly listing of all proposals affecting registration and reregistration and that HEW is to furnish a similar listing of proposals affecting tolerances. It further provides that USDA and HEW respectively will, upon request, furnish to the other departments full information about any pending action on registration or the setting of a tolerance.

The agreement also specifies that questions concerning any item on the weekly listings are to be communicated to the originating department within one week, stating the specific reason for need for further review. The originating department is then required to furnish the necessary information and make the necessary arrangements for further review and to withhold final action on the matter questioned for an additional 3 weeks.

If one department concludes that a proposal should be rejected in whole or in part, the agreement provides for the objection to be expressed in writing and supported by appropriate scientific evidence.

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Upon such notification, the agreement requires the department responsible for final action to take the initiative to work out a basis for agreement. In the event agreement is not reached among the department representatives within 2 weeks of the initial objection, the agreement provides for the matter to be referred directly to the Secretary of the department responsible for final action with such information, views and recommendations as the representatives of the three departments deem appropriate. The agreement further provides that the Secretary charged with final action will notify the other two departments in advance of the proposed final determination of the issues.

Departmental representatives responsible for implementing the agreement are required to jointly make a quarterly report concerning their activities to the Secretaries of the three departments. The agreement also requires that a general conference be held at least once each year—

> to discuss research needs, research program and policy, and the application of research findings in action programs, including public information relating to pesticides.

Registration of pesticides over objections

At a subcommittee hearing on May 7, Dr. Harry W. Hays, Director of the Pesticides Regulation Division, was asked how many pesticide products were currently registered by PRD for marketing although the Public Health Service or some other Government agency had expressed doubt concerning their safety or effectiveness. Dr. Hays gave the following response:[23]

> Well, we have some 45,000 products registered with the Pesticides Regulation Division and of that I don't think there is more than—I really don't know. I would say a half dozen in which the Public Health Service has expressed some concern.

Further inquiry by the subcommittee disclosed that neither the Pesticides Regulation Division nor the Public Health Service actually knew how many such products are being marketed. USDA witnesses admitted at a later hearing that no separate records were kept to identify products registered over PHS objections and that it would be necessary to make an extensive review of individual files to identify such products. HEW witnesses told the subcommittee that they did not know how many products to which they had objected were on the market because USDA did not inform them of the action taken concerning their objections. (The mere fact that a product to which PHS objected was registered did not necessarily mean that an objection had been ignored, since some objections could have been resolved by requiring a change in labeling prior to registration.) [26]

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[23] Hearing record, p. 23.

While the total number of pesticide products being marketed over PHS objections is not known, it is obviously many times larger than the "half dozen" suggested by Dr. Hays' testimony on May 7. USDA subsequently advised the subcommittee that during fiscal year 1969 alone, "there were 185 registrations or reregistrations that appear to have been issued over Public Health Service's objections." [27]

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During a 5-year period from July 1, 1964, through June 30, 1969, according to figures furnished by USDA, a total of 1,633 objections to proposed registrations or reregistrations were made by PHS. The number of objections reported for each of the 5 fiscal years included in this period ranged from a high of 545 in fiscal 1967 to a low of 185 in fiscal 1969.[28]

USDA cited the decrease in objections in fiscal 1969 from prior years as evidence it had made use of many of PHS' objections. HEW contended, on the other hand, that its review indicated USDA was registering practically all products objected to and that USDA figures showed more products registered over HEW objections in some years than the number of objections actually made.[29]

Noncompliance with provisions of agreement

Dr. George W. Irving, Administrator of the Agricultural Research Service, told the subcommittee that he felt that ARS had adequately considered objections made by the Public Health Service to products proposed for reregistration. Dr. R. J. Anderson, the Associate Administrator, stated in testimony concerning the interdepartmental agreement that the advice and recommendations of HEW and the Department of Interior "are considered and weighted carefully in connection with the decision to register or refuse registration of a product." [30]

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[26] Hearing record, pp. 73–74, 125, 133.

[27] Hearing record, p. 301.

[28] Hearing record, p. 302.

[29] Hearing record, pp. 301–302.

Further investigation by the subcommittee indicated that PHS officials took a much less optimistic view of interagency cooperation under the agreement. Toward the end of 1964, Dr. Daniel I. Mullally of the PHS Office of Pesticides wrote a memorandum to Dr. Howard Bond, Chief of the Office's Registration Staff, concerning a November 20, 1964, meeting with Justus Ward, then Director of the USDA Pesticides Regulation Division. In concluding the memorandum, Dr. Mullally stated that:

> In summary, this meeting and other developments before and since this time, have only served to confirm my opinion that the Registration Division of the USDA has no intention of complying with the spirit or even the letter of the terms of the interdepartmental agreement.

Dr. Mullally's concern appears, in retrospect, to have been justified. Item 2(e) of the interagency agreement provides that:

> In the event agreement is not reached among the department representatives within 2 weeks of the initial objection, the matter will then be referred directly to the secretary of the department responsible for final action * * *.

However, the subcommittee investigation disclosed that not a single one of the more than 1,600 objections made by HEW was referred to the Secretary of Agriculture. Dr. Irving told the subcommittee that ARS felt they had resolved the issues involved in the objections by allowing the products to be placed on the market and that there consequently was no need to refer the matters to the Secretary.[31]

Failure of the Pesticides Regulation Division to comply with the provisions of item 2(e) were called to the attention of the Agricultural

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Research Service in a November 1965 report by a task force assigned to review registration and enforcement procedures of the Division. The report cited the requirement that objections be referred to the Secretary "in the event agreement is not reached among the department representatives within 2 weeks of the initial objection," and stated flatly that "this has not been done." The report was submitted to Dr. R. J. Anderson, ARS Associate Administrator, on November 19, 1965.[32]

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[30] Hearing record, pp. 11, 72–73.

[31] Hearing record, pp. 66, 71.

Chairman of the 1965 task force was Dr. Harry W. Hays, then Director of the Advisory Center on Toxicology for the National Academy of Sciences-National Research Council, who was subsequently named Director of the Pesticides Regulation Division. When asked whether he remembered the 1965 comment by the task force on item 2(e), Dr. Hays responded that:

> I really don't recall, sir. I have not reviewed that report for some time.[33]

The subcommittee subsequently located a September 29, 1965, memorandum from E. P. Reagan, Acting Deputy Administrator, ARS, to Carl Barnes, USDA Director of Personnel, giving details of the task force study and the particular areas of inquiry to each individual member. The memorandum stated that:

> Dr. Hays personally looked into operations under the [interdepartmental] agreement * * *.

Item 3 of the interdepartmental agreement provides for a general conference of departmental representatives to be held at least once each year. However, testimony at subcommittee hearings disclosed that not one such meeting had been held during the more than 5 years since adoption of the agreement.[34]

Evidence of continued lack of cooperation

The General Accounting Office reports concerning operations of the Pesticides Regulation Division were issued in September 1968 and February 1969. At its May 7, 1969, hearing, the subcommittee was informed that a meeting of representatives of USDA, HEW, and Interior had been held on March 19, 1969. One of the purposes of the meeting, the subcommittee was told, was to help resolve differences of opinion among departmental representatives and to improve cooperation in connection with the agreement.[35]

While the March 19 meeting may have been a step in the right direction, it clearly did not bring about complete cooperation. The subcommittee found that on March 21, 1969, 2 days after the meeting, Dr. Thomas H. Harris, Director of the Division of Pesticide Registration, Food and Drug Administration (which now has responsibility for label review activities formerly assigned to the Public Health Service) addressed a letter to the USDA Pesticides

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[32] Hearing record, pp. 248, 287.

[33] Hearing record, p. 28.

[34] Hearing record, pp. 71, 128.

[35] Hearing record, pp. 5, 27.

Regulation Division requesting information relating to whether or not certain pesticide products to which objections had been made were currently registered. A file memorandum prepared by Dr. Harris indicates that no answer to the letter had been received as of April 2 and that Dr. Harris called PRD on that date "to ascertain whether or not this information would be forthcoming." According to the memorandum, Dr. Harris was informed that Dr. Harry W. Hays, Director of the USDA Pesticides Regulation Division, would call him. Dr. Hays, according to the memorandum, asked why FDA wanted the information and was told that it was needed in order to ascertain whether the product involved had been registered over HEW safety objections. Dr. Harris' memorandum gave the following account of the remainder of his telephone conversation with Dr. Hays:[36]

> Dr. Hays said that the information requested was, in his opinion, not related in any way to the requirements in the agreement and that the agreement did not require that PRD furnish us with such information. I reminded Dr. Hays that paragraph 1, information, page 2 of the agreement states in part, "Upon request, the Departments of Agriculture and Health, Education, and Welfare, respectively, will furnish to the other departments full information about any pending action on registration or the setting of a tolerance." To this he did not comment.
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> Dr. Hays told me that as a result of the two General Accounting Office reports he was suspicious of everybody and that he thought the GAO was out to get him. He claimed that certain members of his staff had been misquoted in the GAO reports and that from now on any information that came out of PRD would be very carefully screened by him beforehand. He said that if he gave us the information requested in our letter he was of the opinion it would be used against him.
>
> I asked Dr. Hays if all this meant that we could not expect to receive this information. He replied, "I didn't say that." I then asked when we could expect to receive the information. He replied, "I have no idea." I asked if this meant that it might be 6 months before we could expect to obtain the information and he said, "I cannot tell you. I have no idea." At this point I thanked him and told him that I had another matter that I would like to discuss with him.

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[36] Hearing record, pp. 131–132.

Misconception of burden of proof

The subcommittee investigation indicated that a significant factor in the registration of such a large number of pesticide products over unresolved safety objections was a basic misunderstanding by USDA officials of the legal requirement that pesticides must be shown to be safe before being registered.

In the discussion of lindane earlier in this report, it was noted that USDA officials—although admitting that it was the responsibility of would-be registrants to establish the safety of their products—conducted themselves as though products should be registered unless those opposed proved them to be hazardous. This pattern of conduct was not limited to lindane products.

Dr. R. J. Anderson, Associate Administrator of the Agricultural Research Service told the subcommittee that: [37]

> The current legislation, amended in 1959 and 1962, is based on the concept of protecting the public and our total environment from possible hazards created by the use of economic [p. 38] poisons. Registration procedures require proof of the safety and effectiveness of a material before it is marketed in interstate commerce.

Other statements by USDA officials, however, indicated that this policy was not followed. Dr. George W. Irving, ARS Administrator, told the subcommittee that:

> * * * the action we take is to register in the absence of evidence to indicate it shouldn't be.

Dr. Ned D. Bayle, USDA Director of Science and Education, told the General Accounting Office in a November 27, 1968, letter that lindane products had been registered over objection of the Public Health Service because:

> * * * ARS felt that the evidence was not sufficiently well documented * * * to refuse registration.[38]

Prior to early 1964, there might have been some basis for a belief that it was necessary to show a pesticide was hazardous to justify refusing registration of a pesticide product which had not been clearly demonstrated to be safe. Until then, the Federal Insecticide, Fungicide, and Rodenticide Act required USDA to register a product under protest, if the applicant insisted, even though USDA did not believe it had been shown to be safe. The registrant could then sell the product to the public unless and until USDA was able to develop legally acceptable proof to justify a court decision to remove the product from the market. However, Public Law 88-305, signed by the President on May 12, 1964, amended FIFRA to eliminate protest registration and make it clear that the burden of establishing the safety of a pesticide must be met by the applicant before it could be registered.

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[37] Hearing record, p. 2.

[38] Hearing record, pp. 65, 216.

Although officials of the Pesticides Regulation Division completely ignored some provisions of the interdepartmental agreement—such as the one requiring unresolved objections to be referred to the Secretary—there was at least one conspicuous exception. Section 2(d) of the agreement provides that if a department concludes that a registration proposal should be rejected, this view shall be expressed in writing and "supported by appropriate scientific evidence." When the agreement was adopted, in March and April 1964, pesticides could still be marketed under protest registration; under then existing law, evidence of hazard might be useful or even essential in keeping a particular pesticide off the market. Since May 1964, however, the law has clearly required that the safety of pesticides be established before they are registered; in the absence of adequate evidence of safety, a product cannot legally be registered even if there is no proof that it is hazardous. Interagency agreements cannot, of course, contain requirements which contravene mandatory provisions of the statutes. Nevertheless, USDA has consistently taken the position that it was free to ignore safety questions raised by HEW unless it was furnished with scientific proof that the pesticide involved was hazardous.

FOOD ADULTERATION

Statutory prohibition of food adulteration

The Federal Food, Drug, and Cosmetic Act prohibits adulteration of food in interstate commerce.[39] Under the act, a food is deemed to be

[p. 39]

adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; if the substance is not an added substance, however, the food is not considered adulterated if the quantity of such substance in the food does not ordinarily render it injurious to health.[40] If, on the other hand, the food contains an added poisonous or deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity, a food additive or a color additive), it is considered to be adulterated under the act regardless of whether or not it would be injurious to health except where such substance is required in the production of the food or cannot be avoided by good manufacturing practice.[41]

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[39] 21 U.S.C. 331.

[40] 21 U.S.C. 342(a)(1).

Although not covered by the general prohibition against any added poisonous or deleterious substances, a pesticide chemical in or on a raw agricultural commodity is considered under the act to adulterate such commodity, if the chemical is not generally recognized by experts as safe, unless a tolerance for the chemical has been issued and the amount is within the tolerance or unless the chemical has been exempted from the requirement of a tolerance with respect to use on the commodity. Under the act, the Secretary of Agriculture is responsible for determining whether a pesticide chemical is useful to agriculture when used as proposed, and the Secretary of Health, Education, and Welfare is then responsible for determining a safe tolerance—which may even be zero.[42]

A food additive is defined in the act as any substance not generally recognized by experts as safe:

> The intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.[43]

A poisonous or deleterious substance which is a food additive is considered under the act to adulterate food unless a regulation has been issued by HEW prescribing the conditions under which such additive may be safely used and its use conforms with such regulation or unless it has been exempted from the requirements of the act for investigational use by qualified experts. Where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption or tolerance, the residue of such chemical remaining in or on processed food is not considered to adulterate the food if the residue has been removed to the extent possible in good manufacturing practice and the concentration of the pesticide residue in the processed food is not greater than the tolerance prescribed for the raw commodity.[44]

Approval of pesticide uses likely to contaminate food

The Food and Drug Administration has primary responsibility for enforcing provisions of Federal law prohibiting adulteration of food. However, the Department of Agriculture plays—or should play—a significant role in preventing adulteration of food by pesticides. In accordance with a recommendation of the President's Science Advisory Committee on Use of Pesticides, HEW and USDA jointly contracted with the National Academy of Sciences-National Research Council to [p. 40] make a study of problems involved in regulating pesticide residues on food. The study was made by a pesticides residue committee under the chairmanship of James H. Jenson, president of Oregon State University; the Committee's secretary was Dr. Harry W. Hays. In a June 1965 report, the Committee gave the following description of USDA's position with respect to registration of pesticides which might leave residues on food:

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[41] 21 U.S.C. 342(a) (2) (A); 21 U.S.C. 346(a).

[42] 21 U.S.C. 342(a) (2) (B); 21 U.S.C. 346(a).

[43] 21 U.S.C. 321(s).

[44] 21 U.S.C. 342(a) (2) (C); 21 U.S.C. 348.

> The Federal Insecticide, Fungicide, and Rodenticide Act carries no specific provisions relating to the contamination of food. However, in administering the act, the U.S. Department of Agriculture has taken the position that directions for use of a pesticide are not adequate to protect the public if any use of it might leave a residual amount of the pesticide on food or feed crops that would make them subject to action by the Food and Drug Administration.

However, the subcommittee investigation disclosed that USDA's Pesticides Regulation Division had registered pesticides for uses which were obviously likely to result in illegal residues on food.

An example, which has been discussed previously in this report, was the registration of lindane for use in continuous vaporizers in restaurants. Because such products kill insects by filling a room with pesticide, it is obvious that a residue of the pesticide could be expected in any exposed food in the room—in fact, it would be most surprising if there were no residue under such conditions. USDA not only should have anticipated that lindane vaporizers would leave residues on food in restaurants, but was provided with an FDA study in 1953 which concluded that such residues would result. Nevertheless, USDA continued to register and reregister lindane for use in continuous vaporizers in restaurants for more than 15 years. When USDA finally made its own tests, after release of a GAO report criticizing continued registration of lindane, it took only 5 days to establish that residues would result.[45]

Another example involved the registration by PRD of the Shell Chemical Co.'s "No-Pest Strip" and substantially identical products distributed by other companies. The active ingredient of the "No-Pest Strip" is vapona, Shell's trade name for the chemical 2,2-dichlorovinyl dimethyl phosphate, which is also known as DDVP or dichlorvos. In the "No-Pest Strip," vapona is incorporated into a resin which is molded into plastic strips and sealed into an envelope of metal foil. After removal of the wrapper, vapona is released slowly from the strip; according to the label, the strip retains its insecticide properties for up to 3 months. Directions for use call for one strip for each 1,000 cubic feet of space.

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[45] Hearing record, pp. 30–31, 87.

Although the "No-Pest Strip" did not utilize an electrical vaporizer, as did lindane products, the purpose of the strip was similar—to fill a room with a sufficient concentration of pesticide to kill insects. Despite the obvious likelihood that residues would be left on food, the Pesticides Regulation Division registered Shell's vapona strip and similar products beginning in 1963 for use in restaurants and other places where food is customarily left uncovered. The registration was continued even though tests made by Shell disclosed that vapona strips [p. 41] did leave residues of DDVP on exposed food and USDA officials responsible for meat inspection would not allow use of the strips in meat processing establishments.[46]

The subcommittee investigation disclosed that USDA had not submitted proposed registrations and reregistrations of either lindane vaporizers or vapona strips to FDA for a determination as to whether or not any proposed use would result in illegal pesticide residues on food. Moreover, the investigation indicated that it was questionable whether FDA, if requested to do so, would have authority under the Food and Drug Act to issue a tolerance or a regulation allowing pesticide residues on food in restaurants. While tolerances for pesticide residues on raw agricultural commodities may be granted, many of the food items normally served in restaurants would not be considered "raw agricultural commodities." (The term "raw agricultural commodity" is defined in the Food and Drug Act as "any food in its raw or natural state.") The law authorizes FDA, under certain conditions, to issue regulations permitting the use of pesticides as food additives. However, FDA advised the subcommittee that it is not clear that this would be permissible in the case of vapona.[47]

The subcommittee found that FDA had refused to approve a tolerance for residues resulting from a device which was to release a mixture of pyrethrins and piperonyl butoxide in food processing areas on an intermittent basis. In an October 10, 1963, letter to the attorney for the applicant for the tolerance, J. K. Kirk, Assistant Commissioner, FDA, made the following comments:

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[46] Hearing record, p. 99.

[47] Hearing record, pp. 80, 87, 90, 91.

> * * * it is our view that the terms of the Food Additives Amendment are such as to preclude the establishment of any tolerance for a food additive in or on a food at a level higher than reasonably required to accomplish the effect intended. In this case we have a petition which is not limited to a specific food product; neither is there, in our opinion, a demonstration that the tolerance sought by your client is the result of the use of the pesticide in an amount reasonably needed to rid the establishment of flies.
>
> On the contrary, we have before us a proposal for applying this pesticide in all sorts of food producing and handling establishments through a metering device which will add the pesticide at frequent intervals, whether or not there is a demonstrated need for that amount of the pesticide at any particular time.
>
> It is our view that the tolerance sought by your client for the residual pesticide resulting from the use of his device is not contemplated by the terms of the statute * * *

Whether or not it could legally have done so, FDA unquestionably has not issued a tolerance for residues of lindane or vapona on food in restaurants. And, since there are no tolerances, such residues clearly constitute illegal adulteration of food.[48]

FDA–PRD action relating to residues from vapona strips

Earlier in this report, it was noted that the Department of Agriculture has initiated action to cancel registrations permitting sale of

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lindane pellets for use in continuous vaporizers. After the subcommittee hearings, USDA also initiated action to require labeling of vapona strips to carry more specific warnings against food contamination.

During his testimony, Dr. George W. Irving, Administrator, ARS, assured the subcommittee that if FDA took the position that a particular pesticide use would result in food adulteration, ARS would accede to this position and require such labeling changes as were necessary to prevent such adulteration. FDA witnesses advised the subcommittee at its June 24 hearing that a review of the registration of vapona strips would be made.[49]

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[48] Hearing record, pp. 88, 138.

On August 6, 1969, FDA informed the USDA Pesticides Regulation Division that FDA's review of residue data submitted by the Shell Chemical Co. for vapona strips—particularly a 1964 study conducted in New Jersey—had led it to conclude:

> * * * That the use of these strips in accordance with label directions will result in contamination of exposed foods.

FDA further advised PRD that:

> As you know, the registered label for this product bears the statement "Do not contaminate food, water, and foodstuffs" but no information is present on the label specifying just how this contamination can be avoided. We conclude that the contamination feature calls for clearcut additional instructions warning against using the strips in areas where food is prepared or served; for example, "Do not use in kitchens or dining areas" and also include a specific restaurant prohibition.
>
> We are bringing this matter to your attention with the belief that you will want to require the registrants to amend these labels in such a manner as to avoid contamination of feed, water, and foodstuffs.

The Pesticides Regulation Division has advised the subcommittee that all firms which have registrations for vapona strips have been informed that labels must be revised to bear the warning "Do not use in kitchens, restaurants, or areas where food is prepared or served."

LABELING OF PESTICIDES

PRD approval of confusing and contradictory labeling

The Federal Insecticide, Fungicide, and Rodenticide Act prohibits the interstate shipment of any economic poison which is misbranded. The act provides that the term "misbranded" shall apply to any economic poison if the labeling accompanying it does not contain directions for use which, if complied with, are adequate for the protection of the public. It also designates an economic poison as "misbranded" if any information required by or under the authority of the act to appear on the labeling is not placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The act further provides that no economic poison shall be registered until it has been determined that the poison's labeling complies with the applicable provisions of the act.[50]

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[49] Hearing record, pp. 97, 126–127.

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During the earlier stages of the subcommittee's investigation, its study raised questions concerning the adequacy of labeling which had been approved for several products. For example, products containing thallium sulfate, a highly toxic ant and rat poison, bore warnings that the poison should be kept away from children and pets; however, the directions for use advised that it be placed on floors and in other places accessibile to rats and ants—and obviously accessible to children. Products containing lindane and vapona bore warnings against contamination of food, but their labels indicated they were approved for use in restaurants under conditions practically certain to result in contamination of any exposed food.[51]

In view of these questions, Dr. Harry W. Hays, Director of the Pesticides Regulation Division, was asked at the subcommittee's June 24 hearing whether he was confident that products presently being approved for registration were being screened carefully enough so that such obviously contradictory labeling could no longer get by. Dr. Hays responded as follows: [52]

> I think we are doing the best job possible, Mr. Chairman, in screening not only the labels but in reviewing and reviewing again, all the data submitted with that particular application, to make certain that the precautionary labeling is consistent with the data and that the directions for use are adequate.

Despite Dr. Hays' confidence, the subcommittee found that labeling for a concentrated fly and roach spray manufactured by the Hysan Products Company of Chicago had been approved (USDA Reg. No. 334–294) after the subcommittee's first hearing although it bore obviously contradictory warnings and directions for use. The warning notice on the label cautions the user to: [53]

> Use in well ventilated rooms or areas only. Always spray away from you. Do not stay in room that has been heavily treated. Avoid inhalation.

However, the directions for use instructed the user to:

> Close all doors, windows, and transoms. Spray with a fine

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[50] Hearing record, pp. 223–224, 227, 229.
[51] Hearing record, pp. 19–20, 23, 61, 96–97.
[52] Hearing record, p. 62.
[53] Hearing record, p. 63.

> mist sprayed freely upwards in all directions so the room is filled with the vapor. If the insects have not dropped to the floor in 3 minutes repeat spraying, as quantity sprayed was insufficient. After 10 minutes doors and windows may be opened.

Misleading effectiveness claim

In addition to poisons bearing inadequate safety warnings and directions, the act designates an economic poison as "misbranded" if its labeling bears any statement relative to the product which is false or misleading in any particular.[54]

Since disinfectants are classified by law as economic poisons, such products must be registered by USDA before being sold in interstate commerce. One registered product claiming disinfectant properties is the detergent Cold Power which has been widely advertised as "germproofing" clothes even when used in cold water. Labeling [p. 44] approved for this product by the Pesticides Regulation Division makes the claim that it "germproofs."

Under questioning at subcommittee hearings, Dr. Hays testified that Cold Power would not kill germs and would at most only inhibit the growth of bacteria. Dr. Hays further acknowledged that the ordinary individual would regard a substance which "germproofs" as one which is proof against germs, rather than one which simply inhibits their growth.[55]

On July 7, 1969, USDA announced that "germproofing" claims would no longer be accepted on labels unless data was furnished to show that the product involved "will impart self-disinfecting properties."

University of Illinois study of pesticide labeling

The subcommittee was informed during its investigation that the Pesticides Regulation Division had arranged for an in-depth study of pesticide labeling to be made by the University of Illinois. The study is being performed under a contract entered into on June 19, 1968, which provides for a study to be completed by May 31, 1970, at a cost of $52,000.

As might be expected, personnel working on the University of Illinois project had not—as of mid-1969—reached any formal conclusions as to the adequacy of pesticide labeling nor made recommendations concerning methods of improving it. However, in a report covering activities from January 1 to March 31, 1969, they reported that a nearly completed review of literature relating to pesticide labeling had given them "* * * a broad view of the dimensions of the problem of studying the communication effectiveness of pesticide labels."

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[54] Hearing record, p. 223.

[55] Hearing record, pp. 38–39.

The problem, as perceived by the project investigators, is rather basic. According to the report, their review of literature indicated first "that most of the pesticide users do not read pesticide labels" and second that "* * * in general, users find it difficult to understand pesticide labels when they read them."

PESTICIDE POISONINGS

Reliance on accident reports to detect dangerous products

In his testimony, Dr. Harry Hays indicated that the Pesticides Regulation Division placed considerable reliance on accident reports as a means of detecting dangerous pesticides, particularly those products with potential hazards which might not have been fully apparent at the time of registration. Dr. Hays told the subcommittee that:[56]

> * * * For any accident that is associated with any pesticide we have a complete review by a group that I have assigned to this task. It is their responsibility to review every accident, regardless of what it is, to determine what the cause may have been and what we could have done to prevent it perhaps through labeling, whether it was an accidental ingestion, whether it was a suicide attempt, no matter what it was.

USDA was asked to submit for the record a description of its arrangements for receiving reports of pesticide poisoning and its evaluation of how well these arrangements were believed to be working. The

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material submitted indicated that the accident reporting network had been established in 1966 and consisted of personnel of three units of the Agricultural Research Service—the Plant Pest Control Division, the Animal Health Division, and the Pesticides Regulation Division—and the Pesticide Coordinators of the Federal Extension Service. Although the ARS Plant Pest Control Division is presently designated as coordinating office, the subcommittee was advised that it is proposed that this responsibilty be transferred to the Pesticide Regulation Division. The subcommittee was informed that "the reporting system appears to be working very well * * *."[57]

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[56] Hearing record, p. 20.

Seriously inadequate information on pesticide poisonings

Further inquiry by the subcommittee disclosed that USDA received reports of approximately 150 to 175 pesticide poisoning incidents during 1968. However, the subcommittee was told that only 52 of these incidents involved humans; the other incidents involved domestic animals, crops, fish, and wildlife, water pollution and other categories. A total of 163 people were involved in the 52 incidents in which poisonings of humans were reported, according to Dr. Hays.[58] When asked his opinion as to how the number of reports received by USDA compared with the total number of pesticide poisonings occurring each year, Dr. Hays responded: [59]

> I don't believe there is any way in which we can really ascertain that figure. I have seen figures that are rather, in my opinion, astronomical. And I certainly don't believe that one report of some 20,000 accidents is anywhere near correct. We are sure we don't receive all reports of all accidents, but I believe we get a fair share of those involving economic poisonings.

Dr. Hay's opinion that the 163 reports of humans being poisoned by pesticides constituted a "fair share" of the total contrasted sharply with information obtained by the subcommittee from the National Clearinghouse for Poison Control Centers, a unit of the Food and Drug Administration. The Poison Control Centers consist of a network of voluntary units throughout the country, usually associated with hospitals, whose primary purpose is to serve as a source of immediate information concerning the manner in which poisoning by various substances should be treated. As a byproduct of their primary purpose, most of the centers furnish reports to the central clearinghouse in Washington concerning the causes of poisoning cases which come to their attention. Officials of the national clearinghouse informed the subcommittee that they receive approximately 5,000 reports of pesticide poisonings annually, about 4,000 of which involve children under 5 years of age. They also advised that, in their opinion, they receive reports on only about one out of every eight or 10 pesticide poisonings.

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[57] Hearing record, p. 38.

[58] Hearing record, pp. 55–57.

[59] Hearing record, p. 55.

Although Dr. Hays told the subcommittee that the Pesticides Regulation Division had been routinely checking with the national clearinghouse to review records on pesticides accidents, he admitted that he was unaware that the clearinghouse received approximately 5,000 pesticide poisonings reports annually or that it prepared computer runs

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listing the number of reports received by type of poison involved.[60]

Dr. George W. Irving, ARS Administrator, told the subcommittee that is was his impression that the number of deaths from pesticides is "very, very small." Neither Dr. Irving nor Dr. Hays was able to provide an estimate as to the total number of deaths resulting from pesticides. However, PRD personnel told the subcommittee that 18 deaths resulted from the 163 human poisonings reported to USDA in 1968.[61]

Dr. R. J. Anderson, Associate Administrator, ARS, told the subcommittee that there has been no central reporting agency within the Federal Government but that a task force of the Federal Committee on Pest Control has now been assigned responsibility for determining what needs to be done to develop a comprehensive and coordinated system for reporting pesticide accidents and injuries.[62] (The Federal Committee on Pest Control is an interdepartmental committee which reviews use of pesticides by agencies of the Federal Government.)

CANCELLATION OF REGISTRATIONS

Legal authority for cancellation of registrations

Before elimination of "protest registration" in 1964, USDA's statutory authority to cancel pesticide registrations was extremely limited. The law authorized cancellation of a registration "in order to protect the public," but required issuance of a registration under protest to replace it.

In 1964, the Federal Insecticide, Fungicide, and Rodenticide Act was amended to provide that a registration may be canceled whenever it does not appear that the registered product or its labeling complies with the provisions of the act. When USDA determines that a registration should be canceled, it is required to notify the registrant of this action and the reasons for it. If the reason for cancellation is one which can be eliminated by corrective action (such as, for example, a change in labeling), the registrant has 30 days after notice in which to take such action; if adequate corrective action is taken within the time limit, there is, of course, no longer any basis for cancellation. If the reason for the cancellation action is not subject to corrective action or if the registrant does not wish to take the requested action, the registrant has two alternatives under the law. The registrant may file a petition requesting that the matter be referred to an advisory committee selected by the National Academy of Sciences or he may request a public hearing; if neither of these actions is taken within 30 days after notice of cancellation, the registration is canceled.[63]

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[60] Hearing record, p. 56.

[61] Hearing record, pp. 58–59.

[62] Hearing record, p. 60.

If referral to an advisory committee is requested, USDA is required "forthwith" to submit all relevant data to the committee. As soon as practicable after such submission, but not later than 60 days, unless the time is extended for an additional 60 days by USDA, the committee is to submit a report and recommendation to USDA as to registration of the product. Costs of the advisory committee may be assessed against the registrant, unless the committee recommends in his favor or the matter was referred to the committee by USDA. After due consideration of the views of the committee and all other data before him, [p. 47] and within 90 days after receipt of the report, the Secretary of Agriculture must make a determination and issue an order with respect to whether or not the registration shall be canceled. If the registrant is dissatisfied with the order, he has 60 days in which to ask for a public hearing.

If a public hearing is held, the Secretary must issue an order with respect to cancellation or modification of the registration within 90 days after completion of the hearing. The order must be based only on substantial evidence of record in the hearing, including the report and recommendations of the advisory committee if the matter was so referred.[64] Such orders are subject to judicial review.[65] In the event of judicial review, the findings of the Secretary as to questions of fact are to be sustained if they are based on substantial evidence in the record.

Five-year failure to adopt rules of procedure

Although the 1964 amendments to FIFRA provided basic legal authority for cancellation of pesticide registrations, this authority could not be utilized in contested cases until rules of practice for hearings had been promulgated. Such rules did not become effective until August 29, 1969, more than 5 years after the amendments were adopted.

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[63] 7 U.S.C. 135b(c); (hearing record, pp. 229-232).

[64] Ibid.

[65] 7 U.C.S. 135b(c) and (d); hearing record, pp. 232-233.

During the 5-year period between enactment of cancellation authority and adoption of procedures to implement this authority, a number of requests for public hearings or referral of a matter to an advisory committee were received. The subcommittee investigation indicated that when such requests were received, efforts to pursue the cancellation action were abandoned and the product involved was simply left on the market.

One instance in which this occurred involved Sibur Mothproof Concentrate, registration No. 1110–1, an arsenic trioxide mothproofing agent for clothes, furs, bedding, rugs, and furniture which was initially registered in 1948. On June 2, 1967, the Public Health Service questioned the continued registration of this product on the ground that serious questions had been raised as to the hazard associated with wearing garments treated with products containing arsenic compounds. On August 30, 1967, the Pesticides Regulation Division notified the registrant that the registration for the product would be canceled within 30 days unless data could be furnished to show that its use would not result in a hazard to persons wearing articles treated with it.

In response to a September 19, 1967, inquiry from an attorney for the registrant asking for clarification, PRD replied on September 25, 1967, that the August 30 letter constituted a 30-day notice of cancellation, but that the 30-day deadline would be extended in the event of a request for a hearing or referral to an advisory committee. On September 28, 1967, the attorney wrote back to request a public hearing.

On January 24, 1968, attorneys for the registrant again wrote the Pesticides Regulation Division asking for confirmation of their belief that, since they had requested a public hearing which had not been held, Sibur Mothproof Concentrate could still be sold legally. On February 15, 1968, PRD replied that: [p. 48]

> Registration for this product has not been canceled and it can still be legally shipped in interstate commerce at this time.

As of August 30, 1969, 2 years after the original 30-day notice of cancellation had been sent to Sibur, no hearing had been held and the product was still registered.

From 1967 until August 29, 1969, when rules of practice were finally promulgated, the subcommittee found that at least 18 other companies had requested public hearings or referrals to advisory committees involving a total of at least 46 products. In each of these cases, so far as the subcommittee is aware, the request had the effect of halting any further cancellation proceedings and the product involved is still on the market.

Inaction by USDA Office of General Counsel

As evidenced by the 5-year delay in promulgation of rules of practice for cancellation actions, the USDA Office of General Counsel took no action on its own initiative to prepare appropriate administrative procedures to implement the 1964 legislative changes. Moreover, OGC apparently ignored a specific request from the Agricultural Research Service that such procedures be established. On April 2, 1968, F. R. Mangham, Acting Administrator, ARS, wrote E. H. Shulman, USDA General Counsel, to advise that a request for a public hearing on a registration had been received by the Pesticides Regulation Division. Mr. Mangham stated that:

> Since the Division has not gone through this procedure since the act was amended in 1964, we would like to know what procedural steps are necessary in granting the hearing as provided under the law.

Although the Mangham memorandum to Shulman asked for "an early opinion on this matter," ARS officials advised the subcommittee that they were unable to locate any reply.

PRD officials also wrote letters in October 1968 to a number of registrants who had requested public hearings or referrals to an advisory committee stating that the Office of General Counsel had been asked to set forth the procedural steps to be followed in granting their requests.

Failure to pursue contested cancellation actions

Since May 1964 USDA has had specific statutory authority to cancel pesticide registrations when the facts warrant such action. Under the law, a registrant who requests it must be granted a public hearing before registration of his product can be canceled. As of the end of September 1962, no such public hearing had ever been held. Administrative procedures for such hearings did not even exist until August 29, 1969.

A large number of registration cancellations have taken place since 1964; however, not one of these cancellations has been the result of a contested cancellation action. Many cancellations have been noncontroversial label changes, fully agreed to or even initiated by the registrant. In other instances, newly available information disclosed a likelihood that previously approved uses might leave illegal residues on food crops and subject such crops to seizure by the Food and Drug Administration; cancellations of these uses were not contested by the registrants.

[p. 49]

The Pesticides Regulation Division did send a number of 30-day notices of cancellation to registrants; if the registrant did not request a hearing or referral to an advisory committee within 30 days, the registration was canceled by default. If, however, the registrant called what amounted to a bluff by PRD by requesting a hearing or referral to an advisory committee, the cancellation proceeding was suspended indefinitely and the product remained on the market.

Two-year delay in cancellation action on arsenic compounds

Even if prompt action were to be taken by USDA, statutory requirements for cancellation of registrations would make a contested proceeding potentially very time-consuming. First, a 30-day notice of cancellation must be given. If referral to an advisory committee is requested, the committee study may take a maximum of up to 120 days after referral. The Secretary of Agriculture has 90 days after the committee reports to make a determination and issue an order; if the registrant is dissatisfied with the order he has 60 days to request a public hearing. After completion of a hearing and issuance of a decision, the registrant could still seek judicial review of an adverse determination. Until the litigation was finally decided, the registration would not be canceled and the product could remain on the market.[96] (A statutory provision permitting suspension of registration under certain circumstances will be discussed later in this report.)

Despite the fact that a contested cancellation proceeding could take many months at best, the subcommittee found that in the case of certain arsenic compounds, USDA resorted to an unnecessary preliminary procedure—which took nearly 2 years—before even starting cancellation proceedings.

On August 1, 1967, the Pesticides Regulation Division notified manufacturers, formulators, distributors, and registrants of pesticides containing sodium arsenite and arsenic trioxide that products containing these substances had been involved in "numerous accidents involving children and domestic animals." (Such products are used primarily as weedkillers, soil sterilizers and, in a few instances, for termite control.) PRD further advised recipients of the notice that products containing more than 2 percent sodium arsenite or 1.5 percent arsenic trioxide would no longer be acceptable for use in or around the home. Although the notice states that labeling of products exceeding the specified percentages must bear a warning against home use and that the label changes "should be initiated as soon as possible," it was not so worded as to constitute the 30-day notice of cancellation required by statute.

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[96] Hearing record, pp. 91–95.

On November 25, 1967, nearly 4 months later, a notice was published in the FEDERAL REGISTER stating, in effect, that the Pesticides Regulation Division was considering issuance of a formal interpretation taking the position already announced in the August 1 notice. The November 25 announcement also stated that interested persons would have 30 days after the date of publication to submit views or arguments concerning the proposed interpretation. PRD informed the subcommittee that the November 25 announcement was made because of resistance to the August 1 position expressed by affected registrants.

On July 25, 1968, 8 months later, a further notice was published in the FEDERAL REGISTER stating that "after thorough consideration of all

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relevant matters" interpretation 25 was being issued. Interpretation 25, which was to become effective 90 days after publication, restated the same position taken in the original August 1, 1967, notice. On October 15, 1968, a few days before interpretation 25 was scheduled to become effective, still another notice was published. It stated that, after the July 25 publication, "additional information was submitted which requires further study," and that the effective date of interpretation 25 was therefore being "delayed until further notice."

During its hearings, the subcommittee requested that it be supplied with any new data submitted between July and October 1968. It was subsequently advised that the data submitted during this period was essentially the same as that previously submitted.[67]

At the subcommittee's June 24, 1969, hearing, when asked the status of the arsenicals matter, Dr. Harry Hays replied that:

> * * * in order to resolve this matter we have referred it to the National Academy of Sciences.

Under further questioning, Dr. Hays admitted that the matter had not actually been referred to NAS, but that the Administrator of ARS had been asked to so refer it. Further testimony made it plain that 1) referral by ARS would mean that USDA would pay the cost of the NAS study; if the study were made at the registrant's request, the registrant could be held responsible for the cost if the results did not support his position; 2) such a referral would not set in motion the cancellation procedures required by law, since this can be done only by a 30-day notice to the registrant; and 3) the registrant might be legally entitled to demand a second NAS study after notice of cancellation if the results of the original study were adverse. Dr. George W. Irving, ARS Administrator, also acknowledged that he had personally concluded a long time ago that the arsenical products were not safe for use around the home.[68]

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[67] Hearing record, p. 110.

On July 17, 1969, USDA announced that the proposed limitations on home use of products containing sodium arsenite or arsenic trioxide were being adopted and that manufacturers were being sent notices that registration of products not in compliance would be cancelled if appropriate label changes were not made within 30 days. USDA did not refer the matter to the National Academy of Sciences during the interim period between the subcommittee's June 24 hearing and the July 17 announcement.

Further misunderstanding of burden of proof

Earlier in this report, it was pointed out that the Pesticides Regulation Division has consistently conducted its operations as though it was required to register a pesticide in the absence of proof that it was hazardous, even though current law clearly places the burden of proof on the would-be registrant to establish the safety of his product. PRD's misconception of the burden of proof has been even more pronounced with respect to cancellation proceedings than in original registrations.

Since termination of "protest registration" in 1964, the basic issue in determining whether or not a pesticide product is entitled to registration—whether the particular proceeding relates to refusal to issue an initial registration or proposed cancellation of an existing one—

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is whether or not the product involved is safe and effective and thereby in compliance with the law. The burden of proving the product is safe and effective is with the manufacturer in either case.

It is apparent, however, that PRD personnel have been acting on the assumption that once a product was registered, the burden of proof shifted and it was up to PRD to prove the product was not safe before the registration could be canceled. Furthermore, PRD personnel took the position that it would be "discriminatory" to refuse to accept new registrations for a product suspected of being hazardous so long as existing registrations for the product had not been canceled.[69]

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[68] Hearing record, pp. 100–108.

POTENTIALLY HAZARDOUS PESTICIDES

No procedures for removing hazardous registered pesticides from market

Earlier in this report, it was noted that Pesticides Regulation Division enforcement branch procedures for removal from the market of hazardous products which were not registered or did not comply with the terms of registration were totally inadequate as of mid-1967 but had been improved substantially since that time. The subcommittee investigation disclosed an equally serious deficiency as of mid-1967 in registration branch procedures for initiating action to remove from the market pesticides which were discovered to be hazardous after being registered. Moreover, as of mid-1969 the subcommittee found no evidence of any real improvement in the latter situation.

Since 1964, the Federal Insecticide, Fungicide, and Rodenticide Act has authorized the Secretary of Agriculture to suspend the registration of an economic poison immediately when he finds that such action "is necessary to prevent an imminent hazard to the public." [70] However, at the time of subcommittee hearings 5 years later, the Pesticides Regulation Division had no criteria for determining whether a particular product was hazardous enough to warrant suspension of its registration so that it could be removed from the market immediately nor did it have established procedures for implementing such a determination. In fact, the subcommittee investigation indicated that only one registration—for a product manufactured by the Aeroseal Corp., Camp Hill, Pa.—had ever been suspended.[71]

Suspension of Aeroseal DDVP strip registration

The one suspension action taken involved a DDVP insecticide strip similar in many respects to the Shell "No-Pest Strip" discussed earlier in this report.

According to testimony by Dr. Harry W. Hays, the registration approved for Aeroseal covered a vapona strip to be manufactured by Shell and purchased from Shell by Aeroseal; the chemical composition of the registered product was to be identical to the Shell "No-Pest Strip." Subsequently, Dr. Hays testified, Aeroseal began manufacturing its own supplies of vapona rather than purchasing the material from Shell. Dr. Hays told the subcommittee that the active insecticide ingredient used by Aeroseal (DDVP) was the same as that used by Shell, but the Aeroseal chemical was impregnated into "blotter paper" rather than resin, as was the case with the "No-Pest Strip." [72]

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[69] Hearing record, pp. 203–205.

[70] 7 U.S.C. 135b(c), hearing record, p. 232.

[71] Hearing record, pp. 85, 94.

Dr. Hays told the subcommittee he was "not completely familiar" [p. 52] with the circumstances leading to PRD action against Aeroseal. Further questioning by the subcommittee disclosed that the case began when representatives of Shell visited the Pesticides Regulation Division to complain about the Aeroseal product. The subcommittee investigation indicated that an official sample of the product was obtained on March 20, 1969, and sent to a PRD laboratory for anlysis. A notice of suspension was issued on March 24, only 4 days later; at the time it was issued no report had yet been received from the laboratory. According to Harold Alford, PRD Assistant Director for Registration, no reports of accidents attributed to the Aeroseal product had been received prior to the suspension notice.[73] The March 24 suspension notice contained the following language:

> We have no information to show that the subject product would be either effective or safe when used as directed. In the absence of such information, we consider the product to be potentially hazardous to persons exposed. Therefore, registration for this product is immediately suspended as provided in section 4(c) of the statute.

Dr. Hays told the subcommittee that his basic reason for concern about the Aeroseal product was that the blotter type material in which DDVP was impregnated might release a higher concentration of DDVP than anticipated and that "the amount in the atmosphere could reach a level that could produce some very serious effects." [74]

Failure to require relabeling of Shell DDVP strip

The Aeroseal DDVP strip and the Shell DDVP strip contained identical active ingredients and similar directions for use; the only significant difference between the two, apparently, was in the material in which the active ingredient was impregnated.[75] There was no such similarity, however, in the speed with which the Pesticides Regulation Division reacted to complaints against the two products.

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[72] Hearing record, p. 81.

[73] Hearing record, pp. 82–84.

[74] Hearing record, pp. 86, 98.

Although Dr. Hays testified that he was "not aware of any specific objections" by the Public Health Service to registration of Shell's "No-Pest Strip," the subcommittee's investigation disclosed that PHS had objected to the registration of DDVP strips from at least 1965 until early 1969. PHS' objection initially was on the ground that DDVP strips deliberately subjected humans to continued exposure to a pesticide. In late 1967, PHS officials decided that the objection to Shell's vapona strip would be withdrawn if an appropriate warning against exposure of infants and aged and infirm persons were placed on the label. Subsequently, the Pesticides Regulation Division informed Shell on several occasions that the warning must be added to the label; however, no action was taken to enforce the PRD demand.

On January 8, 1969, Shell finally agreed to the added warning, but the registration was not amended to reflect the change until April 18, 1969. Under the amended registration, the warning statement "Do not use in nurseries or rooms where infants, ill or aged persons are confined," was required to appear on the label of each "No-Pest Strip." [76] (Further discussion of circumstances involved in the label change appears later in this report.)

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After the change in registration, "No-Pest Strips" which did not bear the required warning statement could not legally be shipped or held for sale in interstate commerce. However, at the time of the subcommittee's hearings in May and June 1969, no action had been taken to remove vapona strips not containing the warning from the market or to require that they be relabeled. When asked about the situation, Dr. Hays commented that, "We don't see any particular need for recalling these." Earlier the same day, it might be noted, Dr. R. J. Anderson, Associate Administrator, ARS, had told the subcommittee that:

> In safety precautions, we are particularly concerned about effects upon young children and older people as the most susceptible segments of our population.[77]

A few days after the subcommittee hearings, Shell was notified that all "No-Pest Strips" must be relabeled to bear the required warning statement.

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[75] Hearing record, pp. 81–82, 86.

[76] Hearing record, pp. 76–77, 83.

[77] Hearing record, pp. 4, 31, 78.

Inadequate procedures for following up cancellation actions

As indicated earlier in this report, the Enforcement Branch of the Pesticides Regulation Division now appears to have reasonably adequate procedures for removing potentially hazardous pesticides from the market through voluntary recalls or multiple seizures when violative products are discovered by Enforcement Branch inspectors. However, the subcommittee found that the PRD had no procedures to insure that the Registration Branch notified the Enforcement Branch in the event a pesticide registration was cancelled or amended for safety reasons.

Moreover, as the earlier discussion in this report of the handling of thallium products and Shell's "No-Pest Strips" makes clear, PRD deliberately left violative products on the market after cancellation or amendment of registrations.

Failure to warn public

The necessity for removing hazardous pesticide products from marketing channels in order to protect the public is obvious. However, even if successfully accomplished, such action would not protect anyone who had already purchased the hazardous product and had it in his home.

The subcommittee investigation indicated that PRD issues routine press releases describing enforcement and cancellation actions and that such notices are distributed to farm-oriented news media. However, the investigation indicated that there were no procedures for warning consumers of specific hazards which came to PRD's attention concerning particular pesticide products. By contrast, it appeared that another unit of the Agricultural Research Service—the Veterinary Biologics Division—took prompt and vigorous action to alert livestockmen to possible hazards to cattle from blackleg—malignant edema bacterin.[78]

In his June 24 testimony, Dr. Hays agreed that the idea of issuing a specific warning notice to the public in every instance where a product on the market may be dangerous "has virtue." [79] USDA subsequently issued warning notices relating to several pesticide products.

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[78] Hearing record, pp. 10–11, 80.

[79] Hearing record, p. 79.

CONFLICT OF INTEREST QUESTIONS

CONFLICT OF INTEREST LAWS AND REGULATIONS

Restrictions on actions of Federal employees

Federal law prohibits certain actions by Government employees affecting a personal financial interest. The basic conflict of interest statute applicable to Federal employees is 18 U.S.C. 208. This section prohibits an officer or employee of the executive branch of the U.S. Government, including a special Government employee, from participating "personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter" in which he has a financial interest. The same prohibition applies, if, to his knowledge, his wife or child or an organization in which he is serving as an officer or employee or with which he is negotiating or has any arrangement concerning prospective employment, has a financial interest.

The penalty for violation of 18 U.S.C. 208 is a fine of not more than $10,000, or imprisonment for not more than 2 years, or both. The restrictions imposed by section 208 may be waived if the officer or employee received a written determination in advance that the financial interest is not so substantial as to be deemed likely to affect the integrity of his services or if the financial interest has been exempted from the requirements of the law by a general rule or regulation as being too remote or too inconsequential to affect the integrity of Government officers' or employees' services.

A "special government employee" is defined for the purposes of section 208 as an officer or employee of the executive or legislative branch of the U.S. Government "who is retained, designated, appointed, or employed to perform, with or without compensation * * * temporary duties either on a full-time or intermittent basis," for not more than 130 days during any period of 365 consecutive days.[80]

USDA regulations relating to employee responsibilities and conduct, in addition to prohibiting actual conflicts of interest, also provide that an employee may not have a direct or indirect financial interest that appears to conflict substantially with his responsibilities and duties as a Federal employee.[81]

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[80] 18 U.S.C. 202(a).

[81] Department of Agriculture Personnel Manual, 735–24(a).

Limitations on activities of former officers and employees

In addition to proscribing acts of present employees affecting a personal financial interest, Federal law also places limitations on activities of former officers and employees.

18 U.S.C. 207(a) makes it unlawful for anyone who has been an officer or employee of the executive branch of the U.S. Government, including a special government employee, to knowingly act after his employment has ceased:

> as agent or attorney for anyone other than the United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other par- [p. 55] ticular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially as an officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, while so employed * * *

The penalty for violation of section 207(a) is the same as that applicable to section 208. The definition of "special Government employee" applicable to section 207(a) is also the same as for section 208.

Under certain circumstances, former officers or employees may be exempted from the coverage of section 207(a); in such cases a written determination that it is in the national interest must be made and published in the FEDERAL REGISTER.[82]

The statute of limitations applicable to prosecutions for violations of sections 207 and 208 is 5 years.[83]

SERVICE OF DR. T. ROY HANSBERRY ON USDA TASK FORCE

Appointment of Shell official to review registration procedures

On July 6, 1965, Secretary of Agriculture Freeman announced the appointment of a seven-member task force to study procedures used by the Pesticides Regulation Division " * * * in determining the safety and effectiveness of pesticides offered for Federal registration." Dr. Harry W. Hays, then of the National Academy of Sciences, was named chairman. The announcement named four USDA officials as members of the task force along with an official of the California Department of Agriculture and one man from private industry. The latter was Dr. T. Roy Hansberry, Assistant Director, Agricultural Research Division, Shell Development Co., Modesto, Calif. The Shell Development Co. is an affiliate of the Shell Chemical Co., a division of Shell Oil Co.

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[82] 18 U.S.C. 207(b).

[83] 18 U.S.C. 3282.

The appointment of Dr. Hansberry to the task force, according to testimony by Dr. George W. Irving, ARS Administrator, was suggested by Dr. Harry W. Hays. Dr. Hansberry had served with Dr. Hays on a National Academy of Sciences committee studying tolerances for pesticide residues. Dr. Irving told the subcommittee that the principal reason for wanting Dr. Hansberry on the task force was so that he could review the procedures, facilities and personnel at laboratories operated by the Pesticides Regulation Division.[84]

Records of the task force are incomplete, for reasons which will be made clear below. However, a September 29, 1965, letter from E. P. Reagan, Acting Deputy Administrator, ARS, to Carl Barnes, USDA Director of Personnel, indicates that the actual duties performed by Dr. Hansberry as a member of the task force related to registration procedures and policies, rather than laboratory operations. The letter states that Dr. Hays, chairman of the task force, had assigned subcommittees to make detailed studies in specific areas. The letter identifies Dr. Hansberry as being assigned to a three-member subcommittee on "Criteria." The assignment of this group, according to the letter, was to make:

> * * * a critical review of the operations of each of the units having responsibility for various phases of registration in order to evaluate the criteria used by each unit in establishing registration in terms of safety and effectiveness.

Hansberry conflict-of-interest clearance

According to information supplied by the Pesticides Regulation Division, Shell Chemical Co. registered a total of 256 pesticide products with PRD from the beginning of the registration program through June 1969. Of these, 162 products were registered before the end of 1965. (The total number of products currently registered by Shell is sustantially less than 256 since a number of product registrations have either been canceled or allowed to expire.)

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In view of the large number of pesticide products it sells—none of which can be sold in interstate commerce unless registration is approved by USDA—the interest of Shell Chemical Co. in PRD registration procedures is obvious. At the time the task force was appointed in 1965, Shell had reason to be particularly concerned about objections being raised to continued registration of its No-Pest Strip. Further details concerning the nature and extent of such objections will be discussed later in this report.

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[84] Hearing record, p. 117.

ARS advised the subcommittee that, under procedures in effect in 1965, prospective consultants were required to submit financial statements which were reviewed from a conflict-of-interest standpoint by the ARS Personnel Division and then forwarded to the USDA Office of Personnel for further review. If there was considered to be a question regarding a possible conflict of interest, the financial statement was to be submitted by the USDA Office of Personnel to the Office of General Counsel.

Despite the extensive dealings between Shell and the Pesticides Registration Division, the clearance form approved by the Office of Personnel bears the typed notation:

> The Agricultural Research Service does not have, or know of, any official business with the persons, firms, or institutions with which Dr. Hansberry has other financial interests as reported on the SF–68 [statement of employment and financial interests] which might constitute a conflict of interest.

Dr. George W. Irving, ARS Administrator, was asked to ascertain who was responsible for the purported ARS clearance statement; he subsequently advised the subcommittee that he had been unable to determine who had made the statement. Max Reid, USDA's Deputy Director of Personnel, testified that Dr. Hansberry's SF–68 could not be located and that there was no record that his employment had been cleared with the Office of General Counsel.[85]

Clearance of the Hansberry appointment contrasted sharply, in some respects, with the manner in which appointment of another man associated with Shell had been handled a few weeks earlier. That matter involved reappointment of Dr. Mitchell R. Zavon to serve without compensation as a consultant to the Pesticides Regulation Division; Dr. Zavon also served, according to his SF–68, as consultant to the Shell Chemical Co. and held stock in a Shell affiliate. On May 7, 1965, Dr. Zavon's SF–68 was forwarded by the ARS Personnel Divi-

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sion to the USDA Office of Personnel with a notation on it "No conflict in ARS." The letter of transmittal contained a specific request that the SF 68 be sent to the Office of General Counsel for clearance. The Zavon SF 68 was transmitted to the Office of General Counsel on May 11, 1965; on May 21 it was returned to the Office of Personnel with a notation that, although there was no apparent conflict of interest, in view of Zavon's connection with Shell Chemical Co. he should be advised of the provisions of Executive Order 11222. This order, promulgated on May 8, 1965, relates to Standards of Ethical Conduct for Government Officers and Employees and includes a specific description of types of conduct prohibited by conflict-of-interest laws and regulations. (Activities of Dr. Zavon involving Shell's vapona strip are described later in this report.)

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[85] Hearing record, pp. 116–118.

The apparent failure of the office of personnel to send the Hansberry appointment to OGC for clearance also contrasts with the handling of the appointment of Dr. Harry W. Hays as chairman of the task force; Dr. Hays' SF 68 was sent to OGC for clearance.

Dismissal of task force secretary

In addition to naming members of the Pesticides Regulation Task Force, Secretary Freeman's July 6 announcement designated Harold G. Alford of the Pesticides Regulation Division as Executive Secretary of the unit. The initial meeting of the task force was held on July 8 and 9, 1965. In his capacity as Executive Secretary, Mr. Alford prepared comprehensive minutes of the meeting. The last page of the minutes, page 28, contains the following paragraph:

> Mr. Alford reminded the group that there are restrictions in the law regarding the disclosure of information relative to formulas and thought that this should be thoroughly understood since Dr. Hansberry is an industry representative. Dr. Hansberry stated that he thoroughly understood the restrictions of the law and felt that no complications would arise.

In response to questions, Mr. Alford testified at subcommittee hearings that when he arrived at the second series of meetings of the task force, he was informed by Dr. Hays that his services were no longer required. Dr. Hays told the subcommittee that he had decided not to have Mr. Alford present because he wanted to have "free and open discussions" and thought it would be better not to have Alford—an employee of the Pesticides Regulation Division—present. Dr. George W. Irving, ARS Administrator, told the subcommittee that Dr. Hays' action in relieving Mr. Alford of his responsibilities was concurred in at the time by R. J. Anderson, then Deputy Administrator.[86]

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[86] Hearing record, pp. 115–116.

Although Mr. Alford's appointment as Executive Secretary had been announced by the Secretary of Agriculture, the subcommittee investigation disclosed no evidence that his dismissal had been approved by—or even made known to—the Secretary. Moreover, although Dr. Hays told the subcommittee he made it clear at a task force meeting that he expected every member to respect the confidentiality of certain types of material, the subcommittee found no evidence that employees who had custody of confidential information were instructed that Dr. Hansberry was not to have access to it.[87]

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Mr. Alford's minutes of the task force's first 2-day meeting give a clear picture of what took place; as might be expected, the minutes indicate that the initial meeting was primarily a briefing and planning session. No minutes were prepared for the subsequent meetings at which decisions were made. Although Dr. Hays testified that he kept some notes,[88] he subsequently advised subcommittee staff members that he had destroyed the notes after completion of the task force report.

Reference to Shell Chemical Co. in minutes of task force meeting

Page 7 of the minutes of the July 8–9 meeting indicates that G. M. Downard, then head of the registration section, explained the registration process to the task force "Using as an example the Shell Chemical Co. as applicant." The minutes do not make clear whether an actual registration application was used or whether Shell's name was used in a hypothetical one. However, an August 4, 1965, memorandum from R. J. Anderson, then ARS Deputy Administrator, to Carl B. Barnes, USDA Director of Personnel, describing the work of the task force, states that "The registration process is being examined as actual applications are processed." At the time, two Shell applications for additional vapona strip registrations were pending.

CONDUCT OF JOHN S. LEARY, JR.

Approval of Shell vapona strip for registration by John S. Leary, Jr.

The initial application for registration of Shell's vapona strip was submitted by the Washington office of the Shell Chemical Co. on January 22, 1963. John S. Leary, Jr., was then Chief Staff Officer for Pharmacology of the Pesticides Regulation Division; as head of the Pharmacology Section, his responsibilities included supervising review of labels to determine whether products proposed for registration would be safe when used as directed. The subcommittee investigation indicated that Leary played a significant part in events involving Shell's vapona strip during his service with PRD.

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[87] Hearing record, pp. 114–117.

[88] Hearing record, p. 116.

PRD records indicate that D. Thomas von Sumpter, a pharmacologist in Leary's section, reviewed the Shell application on February 15, 1963, and objected to the proposed labeling. On February 22, 1963, PRD sent a letter to Shell's Washington office advising that the label should be changed to bear the word "Poison" and a skull and crossbones; this position apparently was taken because a liquid vapona product previously registered had been classified as a substance highly toxic to man which requires such warnings.

Notations in the registration file for Shell's vapona strip indicate that Shell representatives visited the Pesticides Regulation Division to discuss the application on March 6, 1963, and that the objection to the proposed labeling for the vapona strip was withdrawn by Mr. Leary on the same day. On March 7, 1963, registration No. 201–136 was issued for Shell's vapona strip.

1964–65 participation by Leary interest involving vapona

Records in the files of the Pesticides Regulation Division indicate that Mr. Leary met with representative of Shell in early 1964 and on April 14, 1965, to discuss matters involving the safety of vapona. [p. 59] Representatives of PHS also attended the 1965 meeting. PHS records indicate that Leary represented PRD at a September 2, 1964, conference in Sacramento, Calif., at which representatives of the California Department of Public Health expressed opposition to registration of vapona for home use.

ARS–PHS differences concerning vapona and other vaporized pesticides

Documents in ARS and PHS files reflect a considerable amount of controversy between the two agencies relating to the continued registration of vapona (DDVP) and lindane products. In June 1965, PHS wrote ARS to reaffirm its opposition to DDVP-impregnated strips and lindane and pyrethrum vaporizing devices, emphasizing that it had decided to object to such usage patterns "after consultation with numerous scientists and public health officers about this problem." A July 23 reply from Dr. R. J. Anderson, then ARS Deputy Administrator, agreed that opposition to use of vaporized pesticides in homes had "considerable merit from the theoretical viewpoint;" Dr. Anderson stated, however, that

ARS did not have scientific evidence to support cancellation of existing registrations for such pesticides and therefore did not feel it was in a position to refuse to register new products of the same type.

A meeting of ARS and PHS officials was held on August 6, 1965. Subsequent correspondence between the two agencies indicates that PHS officials believed an agreement had been reached for formation of a joint committee to study problems relating to vapona strips, lindane, and pyrethrum vaporizers. ARS, however, took the position that no such agreement had been reached and that if a committee were set up it should be appointed by the National Academy of Sciences. After ARS declined to participate in a joint study, PHS decided to go ahead with its own ad hoc committee.

On October 13, 1965, before the meeting of the PHS ad hoc committee, ARS notified PHS that, in the absence of scientific evidence that presently registered DDVP uses were hazardous, it intended to approve pending applications for additional registrations for such uses. On November 15, 16, and 17, according to PRD records, eight additional registrations for vapona products were approved. Two of the registrations were issued to Shell; the other six were issued to companies which planned to purchase vapona from Shell. (It might be noted at this point that the registrations were approved during Dr. Hansberry's service on the task force studying PRD registration procedures.)

PHS committee opposes use of DDVP

The PHS Ad Hoc Committee on Vaporizing Devices met in Washington on November 19, 1965. The eight committee members present, according to the minutes, consisted of two scientists from the National Institutes of Health, two from universities, two from State health departments (California and New York), one from the PHS Communicable Disease Center (which had played a prominent part in development of DDVP as an insecticide), and one from private industry. After deliberation, all eight committee members recommended against use of lindane in vaporizing devices. Six of the eight also recommended against use of DDVP and pyrethrum vaporizers; the two dissenters were the scientists from the Communicable Disease Center and the one from private industry.

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On September 22, 1966, the report of the ad hoc committee meeting was sent by the Surgeon General to Dr. R. J. Anderson, then Deputy Administrator of the Agricultural Research Service. In the letter of transmittal, the Surgeon General stated that PHS had heard that USDA was considering referral of the matter to the National Academy of Sciences, that PHS wished to endorse such action, and that it would withhold its final recommendation until the report of an NAS–NRC Committee was available. PHS also offered to assist in arranging for an NAS–NRC study if USDA so desired.

Meeting of PRD medical advisers

In early October 1966, Dr. Harry W. Hays, Director of the Pesticides Regulation Division, asked three medical experts to meet in Washington on October 26, 1966, to advise PRD on problems relating to vaporized pesticides. Although the report of the PHS ad hoc committee on this subject had recently been received, the subcommittee found no evidence that copies of the report were provided to the medical consultants. PRD files indicate, however, that they were given copies of a six-page memorandum prepared for Dr. Hays by John S. Leary, Jr. The Leary memorandum, by contrast with the ad hoc committee report, did not oppose continued registration of DDVP strips, lindane, and pyrethrum vaporizers. It did, however, suggest that such pesticide uses not be considered "air pollution" but be regarded as "air additives"—a term defined as meaning substances which are introduced into confined spaces in a highly controlled manner to produce a specified and desirable result.

Dr. Hays advised the subcommittee staff that no minutes of the October 26 meeting were kept. The subcommittee did find a November 3, 1966, letter from one of the participants (Dr. Ted A. Loomis, professor of pharmacy, University of Washington) to Dr. Hays indicating a belief that some suitable authority should accept responsibility for stating whether or not the vaporized pesticides were safe. The letter recommended referral of the matter to the National Academy of Sciences, and indicated that such referral had been discussed at the meeting.

Acceptance of position with Shell by John S. Leary, Jr.

On November 14, 1966, according to USDA records, John S. Leary, Jr., resigned his position with the Pesticides Regulation Division, effective December 31, 1966. In a personnel form dated November 14, Mr. Leary gave his reason for leaving as "To accept a position with the Shell Chemical Co."

USDA records examined by the subcommittee did not disclose when employment negotiations between Mr. Leary and Shell Chemical Co. began.

Leary opposes action against vapona strips

The subcommittee's examination of PRD files disclosed a memorandum from John S. Leary, Jr., as Acting Assistant Chief Staff Officer, Pesticides Safety Advisory Staff, to Dr. Harry W. Hays reviewing the report of the PHS Ad Hoc Committee on vaporized pesticides. The memorandum is dated December 6, 1966, 3 weeks after Mr. Leary notified USDA that he was leaving to accept employment with Shell Chemical Co.

[p. 61]

The Leary memorandum, after criticizing various aspects of the ad hoc committee's work, stated that "The report of the committee serves no useful purpose." The memorandum recommended that the report "should be set aside as inadequate justification for any change in the registration status of these methods of pest control."

Leary represents Shell at 1968 meeting on vapona strips

On March 27 and May 29, 1968, Harold Alford, Assistant Director for Registration, Pesticides Regulation Division, stated in letters to Shell Chemical Co.'s Washington office that a warning against use in rooms where infants or infirm individuals are confined must appear on the label of Shell's vapona strip, Registration No. 201-136. (Circumstances leading to the letters will be discussed further later in this report.) On June 12, 1968, L. E. Mitchell of Shell wrote Alford indicating that Shell would like to discuss this matter with Dr. Hays and would contact him for an appointment in July, at which time Shell personnel who had been doing research overseas on vapona were expected to be in the United States.

The subcommittee's investigation disclosed that a meeting between Shell representatives and Dr. Hays and Mr. Alford of PRD on the above matter took place on July 15, 1968. Dr. Hays and Mr. Alford advised subcommittee staff members that there were no minutes for the meeting, but that Mr. Leary had been there and had taken an active part in it. Correspondence in PRD files also indicates that Mr. Leary was present and that he had submitted material relating to the safety of vapona strips. The subcommittee found in the PRD file for Registration 201-136 a document entitled "Vapona Human Study Evaluation: Literature Review" dated April 26, 1968, which argues that use of vapona strips without a warning for infants and infirm individuals "offers no hazard to human health." A sheet of paper attached to the front cover bore the written notation "Review submitted by Mr. Leary, July 15, 1968."

ACTIVITIES OF DR. MITCHELL R. ZAVON

Utilization of same medical consultant by both Shell and PRD

A number of individuals represented Shell Chemical Co. in dealings with Federal agencies relating to vapona strips. One of the most active of these was Mitchell R. Zavon, previously identified as a consultant to both Shell and the Pesticides Regulation Division.

Dr. Zavon, a graduate of Harvard Medical School, served with the Public Health Service from 1950 to 1957. Since that time he has been associated with the Kettering Laboratory of the University of Cincinnati College of Medicine and has also served as assistant health commissioner for the city of Cincinnati. USDA records indicate that, except for three interruptions totaling about 11 weeks, Dr. Zavon was on the rolls as a consultant to the Pesticides Regulation Division continuously from March 13, 1963 until June 30, 1969. In testimony before a Senate committee on June 25, 1963,[89] Dr. Zavon stated that he was a consultant to Shell and the relationship apparently has continued to the present time. Dr. Zavon's 1963 testimony was presented in his capacity as chairman, toxicology committee, National Agricultural Chemicals Association; the as- [p. 62] sociation was described by its president as a nonprofit organization formed in 1963 "to promote the interests of manufacturers and formulators of pest control chemicals in a manner consistent with the public interest."

Clearance of Zavon appointment

For the purposes of sections 207 and 208, the Federal conflict-of-interest laws, a person who is appointed to perform temporary duties either on a full-time or intermittent basis for not more than 130 days during any period of 365 consecutive days is classified as a "special Government employee;" this classification applies without regard to whether or not such employee receives compensation for his services.[90]

The law does not prohibit a special Government employee who is employed by or has a financial interest in a private firm from transacting business with the Government on behalf of that firm so long as it is unrelated to his present or past Federal employment. However, it does prohibit him from participating personally and substantially as a Government employee in a matter in which the firm has a financial interest. It also prohibits a special Government employee who participates personally and substantially as an employee in a matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest from representing anyone other than the United States in connection with such matter after his employment has ceased.[91]

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[89] Subcommittee on Reorganization and International Organizations, Senate Committee on Government Operations.

[90] 18 U.S.C. 202(a).

Under Federal personnel policies, departments and agencies do not normally appoint an individual to serve as a consultant, adviser, or other temporary intermittent employee for periods of more than 365 days; it is not uncommon, however, for such an individual to be reappointed after expiration of an appointment. Before making such appointments, each Federal department and agency is expected to make its best estimate of the number of days during the following 365 on which it will require the services of the appointee; if the estimate is more than 130 days, the appointee is not to be carried on the rolls as a special Government employee.

USDA records indicate that Mitchell R. Zavon was appointed a consultant to the Pesticides Regulation Division in March 1963, and was regularly reappointed—usually for 1-year periods—thereafter. In some instances, Dr. Zavon's service was not continuous because a current appointment expired a few days before the effective date of reappointment.

In April 1964, in connection with a proposed 1-year reappointment of Dr. Zavon, a financial statement showing his connection with Shell Chemical Co. was forwarded to the Office of General Counsel for review. After reviewing the financial statement, Elmer Mostow, then Director of the OGC Research and Operations Division, advised that a presidential memorandum on conflicts of interest be brought to Dr. Zavon's attention. On April 7, 1964, the USDA Office of Personnel informed the ARS Personnel Division of Mr. Mostow's advice on the Zavon matter and stated:

> Please see to it that the President's memorandum "Preventing Conflicts of Interest on the Part of Special Government Employees," May 2, 1963, is especially called to his [p. 63] attention so that he may avoid any possible conflict of interest between his official duties as a consultant for the Department and as a consultant for the Shell Chemical Co.

Dr. Zavon was reappointed for another 1-year period in May 1965. As indicated earlier in this report, the Office of General

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[91] 18 U.S.C. 207, 208.

Counsel again advised that the conflict-of-interest laws and regulations be specially called to Dr. Zavon's attention, and the USDA Office of Personnel again asked the ARS Personnel Division to take such action. USDA records did not indicate that similar action was taken after 1965.

Zavon scientific work relating to safety of vapona

The subcommittee investigation disclosed that Dr. Zavon, either individually or with others, conducted a number of studies relating to various aspects of the safety of vapona. Published and unpublished reports of some of these studies, as well as private communications from Dr. Zavon, were cited by Shell from time to time to support its contention that vapona strips were safe and that no special warning for infants and infirm persons was needed. Shell also made use of studies relating to vapona performed by other scientists associated with the Kettering Laboratory.

One instance in which Dr. Zavon carried out studies on vapona occurred in 1964. On March 20, 1964, Dr. Zavon wrote John S. Leary, Jr., of the Pesticides Regulation Division referring to "our recent conversation," enclosing descriptions of four proposed studies of vapona strips, and asking Leary for any comments he might care to make on the proposed studies. One of the studies was for the stated purpose of determining whether detectable food contamination occurs from use of vapona strips in restaurants.

According to a November 9, 1964, report prepared by Shell (RES 64–112), the food contamination study involved collection from a Hamilton, Ohio, restaurant of food samples which had been exposed to vapona strips for 1 and 2 hours. The samples were collected under Dr. Zavon's direction in August 1964, and sent to the Shell Development Co., Modesto, Calif., for analysis. No residues of vapona were found, according to the report. (As has previously been noted in this report, studies performed by others did disclose residues resulting from use of vapona strips around food.)

Zavon participation in USDA advisory committee meeting on vapona strips

The subcommittee investigation disclosed that Dr. Zavon's activities on behalf of Shell with respect to vapona strips were obviously not limited to conducting scientific studies. The subcommittee found evidence of numerous contacts by Dr. Zavon with Government officials relating to vapona strips.

Files of the Public Health Service contain notes indicating that a meeting at which vapona strips were discussed was held on April 14, 1965. The notes indicate that participants were Dr. Zavon, John S. Leary, Jr., two representatives of the Public Health Service, and three employees of Shell. Dr. Zavon presumably attended the meeting in his capacity as a consultant to Shell; the subcommittee found no indication in USDA files that Dr. Zavon was acting as a consultant to the Pesticides Regulation Division on that occasion.

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The situation was different at a June 9, 1967, meeting of the Pesticides Regulation Division Advisory Committee. The agenda for the meeting lists the members of the committee as Drs. Victor A. Drill, Bertram D. Dinman, Ted A. Loomis, and Mitchell Zavon. Seven items were listed on the agenda. Items number 3 and 4, respectively, were "Report on Pyrethrum Vaporizers" and "Lindane Vaporizers and DDVP Strips." Minutes of the meeting contain the following statement relating to discussion of lindane vaporizers and vapona strips:

> Dr. Hays said we are still getting reports of adverse reactions from the use of these devices and he raised the question as to whether continuous use of DDVP in a home is needed to control flies. There was considerable discussion regarding lindane and DDVP with no definite conclusions being reached.

USDA records indicate that Dr. Zavon's travel expenses from Cincinnati to Washington and return were paid by the Department of Agriculture and that Dr. Zavon was paid 2 days per diem to cover other expenses in connection with the June 9 meeting.

Zavon contacts with Public Health Service

The subcommittee investigation established that Dr. Zavon, a former medical officer in the Public Health Service, had frequent contacts with PHS personnel in Atlanta and Washington relating to vapona. These contacts occurred both before and after Dr. Zavon's participation in the June 9, 1967, Pesticides Regulation Division Advisory Committee meeting.

Shell opposes PHS study; referral to NAS discussed

Correspondence in PHS files indicates that Shell Chemical Co. actively opposed having the safety of vapona strips studied by either a joint USDA–PHS committee or the PHS ad hoc committee which eventually examined the question. Shortly before the ad hoc committee met, Shell complained to the Surgeon General about the attitude of personnel of the PHS Office of Pesticides toward vapona strips and other vaporizing type pesticides and suggested that, if any study were to be made, it should be by the National Academy of Sciences.

Insofar as the subcommittee is aware, the report of the ad hoc committee, based on its November 19, 1965, meeting, never was released publicly. However, the position of the committee apparently was no secret to the pesticide trade. The November 29, 1965, issue of Food Chemical News reported that the committee had concluded that the use of pesticide vaporizers in the home was dangerous and that PHS would recommend to USDA that such registration be discontinued.

By the time the ad hoc committee report was formally transmitted to USDA by the Surgeon General on September 22, 1966, reports were already circulating that USDA would ask for an NAS study. As previously noted earlier in this report, the Surgeon General stated in his letter of transmittal that PHS had heard USDA was considering referral of the matter to the National Academy of Sciences, that PHS wished to endorse such action, and that it would withhold its final recommendation until an NAS–NRC report was available. Referral to the National Academy of Sciences was also discussed at the October 1966 meeting of the Pesticides Regulation Division's medical advisers.

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Supervisory responsibility for label review transferred to Communicable Disease Center

Around 1949, the Communicable Disease Center of the Public Health Service established a toxicology laboratory at Savannah, Ga., for the purpose of testing and recommending the most effective and safest pesticides for the control of human disease. The toxicology laboratory was associated with the PHS Technical Development Laboratories, which were to become active in the development of DDVP. The toxicology laboratory was moved to Atlanta, Ga., in 1960 as a part of the technology branch of the Communicable Disease Center, which had its headquarters there.

Until August 1966, PHS review of pesticide labels proposed for registration was carried out by the Office of Pesticides, a Washington-based unit of the PHS Bureau of State Services. At that time, supervisory responsibility for PHS label review activities was transferred from the Bureau of State Services in Washington to the National Communicable Disease Center in Atlanta. Actual review of proposed pesticides registrations continued to be performed by a unit in Washington headed by Dr. Thomas H. Harris; Dr. S. W. Simmons of CDC became overall head of the pesticides program.

Dr. K. D. Quarterman, an official of the Communicable Disease Center, had been one of the two members of the ad hoc committee who favored continued registration of DDVP strips. In advocating his minority position, Dr. Quarterman had argued that CDC had devoted a considerable effort over a period of years to developing the concept of using insecticidal vapors for control of disease-carrying insects and that any adverse action with respect to registration of DDVP strips would tend to nullify these efforts.

Zavon requests "re-review" of vapona strips by PHS

On December 21, 1966, Dr. Zavon wrote then Assistant Surgeon General Richard Prindle about the report of the Ad Hoc Committee. Zavon noted that the report had never been made public, but stated that "enough information about its contents has circulated to cause me to write to you about the matter." Dr. Zavon transmitted with his letter a copy of a report on "some of the work my associates and I have done recently" to evaluate the use hazard of DDVP strips. Dr. Zavon went on to endorse DDVP "as a Health Officer" (Dr. Zavon is assistant health commission for the city of Cincinnati) and to suggest that the entire matter of pesticide vaporizers "be re-reviewed by the Public Health Service with opportunity provided for those with experience with these devices to present all of the available information for review." Dr. Zavon's letter made no reference to his relationship with Shell Chemical Co.

Public Health Service files contain a number of letters written by State and local health officers to raise questions about or express opposition to the use of DDVP strips. However, the Zavon letter is the only instance known to the subcommittee in which a health officer wrote PHS to endorse the use of DDVP strips.

Dr. Zavon's letter of December 21, 1966, was referred to Atlanta for reply. On January 4, 1967, Dr. S. W. Simmons, Chief of the pesticides program, wrote Dr. Zavon to advise him that, shortly after taking over the Office of Pesticides, CDC had recommended to USDA that the matter be turned over to the National Academy of Sciences-

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National Research Council. Dr. Simmons further advised Dr. Zavon that CDC understood this had been done.

Zavon negotiates agreement with PHS on vapona strips

Documents in HEW and USDA files indicate that the Public Health Service agreed to withdraw its objection to registration of pyrethrin vaporizers, at a March 1967 meeting in Atlanta with

USDA representatives, but recommended a precautionary statement on the label against exposure of infants, ill and aged persons. The addition of such a precautionary statement apparently was approved by industry representatives at a June 27 meeting in Atlanta, according to a PHS document summarizing the meeting.

On August 21, 1967, Dr. Zavon wrote Dr. David W. Sencer, Director of the Communicable Disease Center, to confirm a telephone conversation earlier in the month. In the letter, Dr. Zavon indicated that there was a reluctance on the part of some State and local health officers to allow use of DDVP strips because of a belief that PHS did not actually agree with the use pattern as registered by USDA. Dr. Zavon enclosed copies of a recently completed report on a 1-year study of the effect of DDVP strips on humans. Dr. Zavon further stated that, if the matter could not be cleared up by correspondence, he and the responsible people from Shell Chemical Co. would be available to discuss it.

A September 12, 1967, file memorandum written by Milton J. Foter, Deputy Chief of the pesticides program, to the Chief, Dr. S. W. Simmons, indicates that Dr. Zavon was in Atlanta on August 28 and 29 during Dr. Simmons' absence to discuss the PHS position relative to a cautionary statement on the label of vapona strips. The memorandum further indicates that Mr. Foter and Dr. Wayland J. Hayes, then Chief Toxicologist for the pesticides program, suggested the label bear the warning "Do not use in nurseries or rooms where infants, ill or aged persons are confined." In addition, the memorandum indicates that Dr. Zavon called Dr. Simmons on September 7, 1967, to discuss the matter and had called Mr. Foter on the morning of September 12. According to Mr. Foter, Dr. Zavon had discussed the proposed warning with representatives of Shell Chemical Co., and they had proposed that the warning read "Do not use in rooms continuously occupied by infants and infirm individuals." Dr. Zavon had requested, according to Mr. Foter, that he be advised by telephone whether the proposed alternative labeling was acceptable and be sent a copy of a typical letter being used to answer inquiries from State health agencies relating to vapona strips.

PHS files contain a copy of a September 11, 1967, letter from Dr. Simmons to the North Carolina State Board of Health stating that personnel of the PHS pesticides program had talked with USDA and Shell Chemical Co. representatives concerning vapona strips. Dr. Simmons further stated that he believed Shell would soon resubmit their label to include the warning "Do not use in rooms continuously occupied by infants and infirm individuals," and that PHS would have no objection to use of vapona strips with such a warning. PHS files indicate that a blind carbon copy of the September letter was sent by Dr. Simmons to Dr. Zavon on September 12, 1967, with a covering note stating that "I believe this is along the lines of our conversation of several days ago."

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USDA refuses to accept labeling proposed by Shell

On Oct. 24, 1967, C. G. Green, Washington representative for Shell Chemical Co. wrote to H. G. Alford, PRD Assistant Director for Registration, requesting approval of a number of changes in the labeling for Shell's "No-Pest Strip"; one of these was the inclusion of the cautionary statement proposed by Shell and agreed to by Dr. Simmons. On November 15, 1967, Mr. Alford wrote Shell to advise that inclusion of the word "continuously" in the statement was not acceptable; Alford's letter indicated that the matter had been discussed in a recent conference. On December 11, 1967, Shell again wrote Alford stating that the company was submitting new data on vapona which it felt eliminated the need for the caution statement and wished to withdraw the request for a change in labeling. The December 11 letter was signed for Shell by L. E. Mitchell, division representative; a copy bore the initials JSL, presumably indicating it had been drafted by John S. Leary, Jr.

Events reflected in the above correspondence are consistent with statements in a brief submitted to the subcommittee by Shell Chemical Co. In the brief, Shell states that it reached agreement with PHS on a cautionary statement through the company's medical consultant, Dr. Mitchell R. Zavon, but that USDA had insisted on deletion of the word "continuously."[92]

Further Zavon contacts with PHS officials in Atlanta

A December 14, 1967, memorandum by Mr. Foter to Dr. Simmons states that Dr. Zavon called on December 13 and talked with Mr. Foter in Dr. Simmons' absence. Dr. Zavon stated, according to the memorandum, that Dr. Harry Hays of the USDA Pesticides Regulation Division "did not see the need" for revising the vapona strip label to include precautionary statements as previously discussed with PHS. In order to resolve the situation, Mr. Leary had written a letter to Dr. Hays with new data on the lack of toxicity of DDVP and Dr. Zavon had asked Mr. Leary to send a copy of the material to Dr. Simmons.

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[92] Hearing record, p. 309.

Mr. Foter also advised Dr. Simmons that Dr. Zavon told him he had received information that the President's Office of Science and Technology had been requested to review the whole problem of pesticide vaporizing devices. According to Foter, Dr. Zavon stated he was not certain of the reliability of his information and encouraged them to make "discreet inquiries" about the matter. The Foter memorandum also indicated that Dr. Zavon had visited the pesticides program offices in Atlanta on November 28 and 29, 1967.

During December 1967 and early January 1968, there was apparently some confusion on the part of the pesticides program registration staff as to the wording of the cautionary statement to be required for vapona strips. (Personnel of the registration section had not participated in the Atlanta discussions relating to the matter.) The registration section informed USDA in commenting on proposed registrations for DDVP products that "We would not object to registration or reregistration of these products if the label bore the statement 'Do not use in nurseries or homes where infants, ill, aged or debilitated people are housed.'"

On January 16, 1968, Dr. Simmons sent Dr. Thomas Harris, chief of the registration section, a memorandum instructing that inquiries

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about vapona strips should be answered by a statement that the pesticides program had no objection to use of the devices in accordance with label instructions, with the additional precautions: "Do not use in rooms continuously occupied by infants and infirm individuals." A second memorandum sent the same day contained the same instructions with respect to use of pyrethrum-piperonyl butoxide aerosol dispensers, except that a stronger precautionary statement was to be required as follows: "Do not use in nurseries or rooms where infants, ill or aged persons are confined."

A further exchange of correspondence between Dr. Zavon and Dr. Simmons in early February indicates that Mr. Leary had been in Dr. Simmons' office and had been shown a copy of the January 16 memorandum on vapona strips. A copy of the memorandum was also sent to Dr. Zavon on February 8, 1968.

Shell personnel meet with officials of Pesticides Regulation Division

Additional notices that a warning against use of vapona strips where infants or infirm individuals might be exposed must appear on the label were sent Shell by PRD in March and May, 1968.

On July 15, 1968, Shell representatives, including John S. Leary, Jr., a former PRD official, met to discuss the matter with Dr. Hays and Mr. Alford of PRD. Details of this meeting have been discussed previously.

On August 7, 1968, M. J. Sloan, manager of regulatory affairs for Shell Chemical Co., wrote Dr. Harry Hays to submit further data on vapona strips. In the letter, Mr. Sloan referred to previous scientific reports "which our medical consultant, Dr. M. R. Zavon, reviewed for you in our recent conference." Dr. Hays informed the subcommittee staff that he did not remember whether Dr. Zavon was present at the July 15, 1968, meeting but that it was possible that he might have been.

Shell agrees to label warning

On September 10, 1968, a report by the Comptroller General which sharply criticized past PRD enforcement procedures was made public. On October 15, 1968, the General Accounting Office submitted a draft of a proposed report on safety questions involving lindane vaporizers to USDA officials for comment. On November 27, 1968. USDA advised GAO that a meeting of PRD's medical consultants was being called to discuss the lindane situation. Further details of these events have been discussed earlier in this report.

On December 10, 1968, PRD notified Shell that it had reviewed the additional data submitted on vapona strips and did not feel the data supported continued use of the product in areas where infants, aged or sick people would be continuously exposed; consequently, the precautionary statement "Do not use in nurseries or rooms where infants, ill or aged persons are confined" must appear on the label. On December 12, 1968, Shell asked that they be allowed to use a statement reading "continuously confined." On January 2, 1969, PRD replied that the alternative wording was not acceptable and that the original statement must be promptly added to the label if registration of the product was to be continued. Both PRD letters bore the signature of Dr. Hays; symbols on the copies indicated the letters were drafted by Harold Alford. On January 8, 1969, Shell wrote PRD that, while it did not agree that the cautionary statement being demanded was necessary, it would comply with PRD's requirement.

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1969 meeting of PRD medical consultants

On January 8, 1969—the same day Shell finally agreed to PRD's demand for a cautionary statement—PRD's panel of medical advisors met in New York. A March 17, 1969, report to Dr. Harry Hays signed by Drs. Victor A. Drill, Bertram D. Dinman and Ted A. Loomis summarized the advisory panel's opinions on questions discussed at the meeting. The panel reported that it was their opinion that the use of vaporized lindane by persons other than qualified pest control operators in areas where food for human consumption is stored or served created a hazard potentially detrimental to human health. Subsequent action taken by PRD to cancel registrations for lindane products has been discussed previously.

The March 17 report also indicated that safety of DDVP strips was discussed at the January 8 meeting, and stated that "No definitive consensus of opinion on this subject was achieved at the meeting of the panel. The available data needs additional comparative evaluation. The subject will be reconsidered at a subsequent meeting."

Dr. Hays informed the subcommittee staff that Dr. Zavon was not at the January 8 meeting in New York and that he himself was the only person there other than the three persons signing the report.

After subcommittee hearings in May and June 1969, USDA took action to require relabeling of Shell "No-Pest Strips" which were being marketed without the cautionary statement called for under its amended registration. USDA has also informed Shell (and other distributors of DDVP strips) that an additional warning against contamination of food must be added to the label. Details of these actions were discussed earlier in this report.

Possible conflict-of-interest question involving dieldrin

When Dr. Zavon was initially appointed to serve as a USDA consultant in March 1963, the description of his duties read in part as follows:

> * * * expert consultant on matters relating to industrial toxicology to confer with and advise the Secretary, the Administrator and Deputy Administrators of the Agricultural Research Service, the Director of the Pesticides Regulation Division, and other officials of the Department on the problem of pesticide usage for plant pest control, specifically dieldrin.

Shell Chemical Co. is a basic producer of dieldrin. As such, it has had a number of pesticide products containing dieldrin registered with the Pesticides Regulation Division since before 1963.

The subcommittee investigation did not disclose whether or not Dr. Zavon actually advised USDA, as an expert consultant, on any matter or matters involving dieldrin in which Shell had a financial interest.

Referral of conflict-of-interest questions to Department of Justice

The subcommittee has been advised by the Department of Agriculture that possible conflict-of-interest questions involving Dr. Hansberry, Mr. Leary and Dr. Zavon have been or will be referred to the Department of Justice.

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QUESTION CONCERNING PATENT RIGHTS

On February 1, 1955, then Secretary of Health, Education, and Welfare Hobby called a press conference to announce the discovery by research scientists at the Savannah, Ga., laboratory of the Public Health Service's Communicable Disease Center of a new insecticide. The insecticide, DDVP, was described as "more potent in killing insects than many modern economic poisons."

In August 1955, an article by Kenneth D. Quarterman, then head of the CDC Savannah laboratory, was published in Public Health Reports. The article contained the following paragraph:

> It has been determined that the Federal Government is entitled to the entire right, title, and interest in the invention of DDVP. It was decided also that the Government should not seek to obtain a domestic patent on the invention because prior publications on the invention by the Government scientists who developed it are deemed sufficient protection against the prosecution of a successful patent application by a later inventor. These publications will, within 1 year from the first date of publication, constitute a dedication of the invention to the public. Such a dedication adequately protects the interests of the Government. On the basis of this determination and decision, any manufacturer who wishes to do so may proceed with the domestic production of DDVP in the United States without seeking a license from the Government.

Despite the statements in the Quarterman article, Shell Chemical Co. now claims exclusive U.S. patent rights to DDVP. The subcommittee has not yet completed its examination of the circumstances on which this claim is based.

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4.2c REPORT ON 2,4,5-T, A REPORT OF THE PANEL ON HERBICIDES OF THE PRESIDENT'S SCIENCE ADVISORY COMMITTEE, MARCH 1971

THE PRESIDENT'S SCIENCE ADVISORY COMMITTEE,
EXECUTIVE OFFICE BUILDING,
Washington, D.C., March 2, 1971

The publication of this report on the herbicide, 2,4,5-T, symbolizes an area of public policy decision-making in which science and, hence, scientists have a large responsibility. The report itself is a landmark. It examines in detail the scientific considerations leading to policy judgments about a pesticidal chemical.

The foresight of Dr. Lee DuBridge, Science Adviser to the President at the time this review was initiated in October 1969, is commendable. The Government agencies charged with responsibilities for regulating pesticides and for overseeing the integrity of the public's health, chose a course of regulatory action in October 1969 which restricted some uses of 2,4,5-T. This action was taken as a result of a new and unexpected research finding which emerged from experiments sponsored by the Government. At that time, Dr. DuBridge perceived the need for a thorough and critical review of all of the scientific information available on the herbicide — including that dealing with biological properties and human health.

Importantly, the report's recommendations already have been adopted by the appropriate Government agencies and specific actions have resulted. The original experiments were confirmed and extended by later research. A potent impurity, a family of dioxins, has been the subject of several research projects. These have taught us more about the herbicide's physical stability, environmental persistence and biological properties. A recommendation for a legislative mechanism to restrict temporarily the use of a pesticide on the occasion of an unexpected research finding implicating it as a health hazard (while further confirmatory research is performed) is reflected in the Administration's proposed legislation on pesticide regulation.

Although the report is concerned with highly technical matters, it does allude to some policy issues. It compares the scientific evidence available, and considered adequate, at the time of first registration of 2,4,5-T with the much greater level of scientific understanding demanded today. The Panel found evidence of measurable benefits from the use of 2,4,5-T but there was simply very little information that could be used to assess risk. Based on its experience in evaluating risks and benefits on the basis of incomplete information, the Panel cautions that judgments on benefits and risks associated with pesticidal chemicals require an unusual measure of prudence to assure that the public is neither subjected to undue risk nor unnecessarily denied the benefits of valuable chemicals.

The report does not speak in particular to the regulatory actions taken by the Government on 2,4,5-T (although I am satisfied that the review complements them in every respect). If any of the Government actions appear divergent from these recommendations, the divergence is consistently on the side of prudence and avoidance of the possibility of hazard to human health, and this is as it should be, for Government must act on the side of prudence. It provides those of us concerned with pesticides, their economic value and utility, their negative effects on the environment, and their other biological effects, with an excellent case study. The principles brought out in this study will be useful in dealing with other pesticides, and indeed with chemicals of other kinds.

EDWARD E. DAVID, JR.,
Chairman

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SUMMARY AND RECOMMENDATIONS

SUMMARY

This review of the herbicide, 2,4,5-T, began with an examination of the results from an experimental screening study which implicated it as a potential teratogen. It quickly became evident that examination from such a restricted basis was inadequate. Therefore, the Panel decided to study more broadly important aspects of 2,4,5-T, including details of its chemistry and purity, its domestic uses and their relative importance, the military significance attached to 2,4,5-T as a defoliant, residue levels (in order to estimate probabilities of human exposure), general effects on the environment, as well as its toxicity. In examining the toxicity of 2,4,5-T, the Panel reviewed the information available from the literature (as well as some unpublished documents) which had been considered in the past in establishing policy decisions for the various uses to which this pesticide had been put.

Selection of 2,4,5-T as an example for detailed examination has had a number of advantages. There has been an extensive history of use and experience. 2,4,5-T was first registered on March 2, 1948, by the Amchem Products Company, Ambler, Pennsylvania. Since that time considerable information on its properties and uses has accumulated. Furthermore, it has been the subject of reviews by others in the past. Finally, the problem which brought it to the Panel's attention, suspicion of teratogenicity, appears to be a relatively manageable problem in contrast to many other biological effects, notably tumor production and genetic alterations. This is important since the recommendations which follow can be made with a degree of confidence that cannot be applied to carcinogenic or mutagenic effects. For example, the dose-response characteristics of teratogens is generally restricted to a relatively small range of dosage. Accordingly, a threshold below which no effect would be expected can be assigned with more certainty. Experiments to determine this range of values can be performed in a relatively short time and do not require very large numbers of animals.

The Panel is gratified that some of its recommendations are already being carried out, especially further experiments to confirm and ex-

[p. 1]

tend the results of the original screening that indicated 2,4,5-T to be teratogenic.

In considering the chemistry of 2,4,5-T, our attention was drawn to impurities which can result from the manufacturing process. Particular attention was focused on a single impurity, 2,3,7,8-tetrachlorodibenzo-p-dioxin, which occurs in commercial preparations of the herbicide in highly variable amounts unless particular care is taken to exclude it. This impurity is extremely toxic. Its amount depends upon variations in the reaction conditions. Other dioxins can be formed from various impurities in the starting materials. The dioxin impurity came to particular attention when the U.S. herbicide industry was asked to produce larger quantities of 2,4,5-T during the middle 1960's. However, its presence as an impurity and certain of its acute toxic effects had been known since 1957. Its concentration in commercial 2,4,5-T has been greatly reduced in the past year or so.

Analytic methods available for 2,4,5-T are accurate and reliable. With the possible exception of citrus fruits, determination of residues in food has not presented a serious analytic problem.

2,4,5-T is relatively labile in nature. Residues in soils and water are not persistent except under unusual conditions. The herbicide is not stored in plants or animals to a significant extent.

Production of 2,4,5-T in the United States rose rapidly between 1960 and 1968. Civilian use, most of which is for clearing of range land and rights-of-way and for treatment of pastures, declined about 50% between 1964 and 1966. Military use of 2,4,5-T as a defoliant, expressed as number of acres sprayed, rose sharply between 1964 and 1967 but has declined since then. Although accounting for only a small amount of the total usage of 2,4,5-T, its place in control of aquatic weeds is significant. There is a small but important list of agricultural uses where 2,4,5-T is applied to food crops. Potential human exposure is recognized in this direct application to food crops, in range and pasture lands grazed by domestic meat and dairy animals, and possibly, in water supplies derived from treated waterways and streams. The economic importance of the various uses is considerable, but is very much less than that of 2,4-D. Substitution of 2,4-D for 2,4,5-T can be made for certain uses.

Defoliation, using mixtures of 2,4-D and 2,4,5-T, has been employed in Vietnam since 1962, more intensively since 1967.

Although not rigorously demonstrated, its military usefulness has been considered to be very high.

The background of toxicological information on 2,4,5-T is thin. Most of the animal studies have been concerned with acute toxicity (single doses or repeated doses for short periods of time). Based on these experiments, the acute toxicity of 2,4,5-T was found to be low. Little is known of the details of the metabolic handling of the material although rapid excretion in the urine seems to be the rule.

[p. 2]

The screening study supported by the National Cancer Institute on the toxicity of certain pesticides and other important industrial chemicals marks an important advance in toxicological testing in that the tests were designed to detect carcinogenic, teratogenic and mutagenic potential. The preparation of 2,4,5-T used in those tests was shown to be teratogenic in both rats and mice. There was no evidence that it was carcinogenic. While this study had a number of limitations which qualified its usefulness, the teratogenic results were sufficiently convincing so that the Panel urged, early in its discussions, that they be repeated and extended using better characterized preparations of 2,4,5-T. Analysis of a sample of the 2,4,5-T preparation used in the original teratogenesis study revealed a dioxin level of about 27 ppm. Such a considerable contamination by this highly toxic material raised the question as to whether the teratogenic effects observed were caused by 2,4,5-T itself, by the dioxin impurity or by other impurities in the commercial preparation tested.

The Panel was aware of press reports of increased birth defects in Vietnam attributed to the use of defoliants. The lack of accurate epidemiological data on the incidence and kinds of birth defects in the Vietnamese population before or since the military use of defoliants precludes any estimate as to whether an increase in birth defects has occurred. Calculations of potential human exposures from sources such as drinking water or direct fallout make this appear unlikely (though theoretically possible).

A review of the environmental effects of 2,4,5-T on nontarget organisms reveals few harmful consequences of its recommended uses. Induced changes in vegetation are followed by alteration in numbers of wild animals. Accelerated erosion of soil may follow the killing of brush with herbicides but mechanical removal causes greater erosion.

RECOMMENDATIONS

1. *Further studies.*

a. *The animal experiments which raised the question of the teratogenic potential of 2,4,5-T should be extended to include a wider range of doses administered to non-inbred strains of animals and to larger numbers of animals.*

b. *The importance of the impurities in 2,4,5-T as potential health hazards should be ascertained.* Recent experiments designed to distinguish between 2,4,5-T and the dioxin impurity have suggested that both the herbicide and the dioxin are potential teratogens in some experimental animals. However, experiments necessary to establish this answer have not been performed. In addition, there may be additional impurities in commercially prepared phenoxy herbicides which may be biologically active.

[p. 3]

c. *The metabolism of 2,4,5-T in humans should be determined and compared to that in experimental animals.*

2. *The level of dioxin, a recognized impurity in 2,4,5-T, should be rigorously controlled and limited to not more than 0.5 ppm.* A reduction to not more than 0.1 ppm should be urged. Several polychlorinated dioxins have been found to be highly toxic and capable of eliciting teratogenic effects, though they vary widely in toxicity. Since they may reach the environment from multiple sources, control over known sources should be exercised to the extent possible.

3. *A decision to restrict the use of 2,4,5-T should not be based on the isolated finding of toxicity but on the expected exposure following recommended use in relation to dose response effects.*

In general, the imposition of restrictions on the use of a pesticide would appear to be a function of two factors, the potential for human exposure and the nature of the toxic effects. For example, if carefully documented residue information points to little likelihood of exposure, the risk of adverse effects would be less significant than if exposure were widespread.

The Panel found no evidence to suggest that significant residues would result from recommended uses of 2,4,5-T on food crops. It is possible for residues to occur in tissues of animals grazing on recently treated pastures and range land. In fact, the only residues which have been identified in the total diet studies have occurred in meat and dairy products. However, the few cases in which residues have been discovered have all been at levels well below those which would be expected to result in significant toxicity for man.

The experimental finding of teratogenesis requires further elaboration before it can be interpreted as a human health hazard.

The risk of teratogenic effects should be placed in perspective. Teratogenesis induced by chemicals is a fetal response at a particularly sensitive period in embryonic development to lower doses of the chemical than are acutely toxic to the mother. Birth defects can be produced in the embryo through many mechanisms of injury when the agents are administered during critical periods of organogenesis. It is generally held that by careful choice of dosage, which may be close to the acutely toxic dose for the mother, most chemicals might be shown to be teratogenic in animals. For a variety of reasons, it is not possible to translate directly the results of experiments in animals to man. There are differences in sensitivity which arise from differences in metabolism. Comparative metabolic studies in man and animals, therefore, are important in interpreting toxicity for man.

The important consideration is not only the demonstration of teratogenicity, which may occur with many chemicals at selected dosages, but the estimation of the likelihood of teratogenic effects with the amounts likely to be ingested incident to recommended

[p. 4]

use. To restrict or ban usage of chemicals on the basis of demonstration of teratogenicity at dose levels which far exceed actual or expected exposures is unreasonable and could well deny usage of chemicals whose benefits far outweigh risks.

4. *Registrations of 2,4,5-T for uses on pastures and range lands should be treated as registrations for food crop uses.*

It is possible for residues of 2,4,5-T to occur in milk and tissues of animals grazing on land recently treated with 2,4,5-T. To date, meat and dairy products have been the only food products in the total diet studies that contained measurable amounts of 2,4,5-T. Use on range and pasture land should be included in registration for use on food crops.

5. *Monitoring of 2,4,5-T residues should be significantly expanded, especially for meat and milk.* In sampling meat and milk, special attention should be given to geographic areas where treatment of pastures and range lands with 2,4,5-T is most common. The 2,4,5-T residues that may occur in meat and milk of animals allowed to graze on pastures and range lands treated according to current recommendations should also be restudied.

6. *As new information is developed on pesticides, it should be disseminated promptly to individuals and organizations that are legitimately concerned as manufacturers, formulators, users and scientific investigators.*

The case of 2,4,5-T is illustrative of inordinate delay in making available new research information as it became known. The screening study of pesticides which was carried out by Bionetics Corporation under contract with the National Cancer Institute was completed about August 1968. It was 14 months later when the Government announced its coordinated actions on restricting the use of 2,4,5-T. It was only after an additional several months that the detailed data of the screening study were made publicly available. A centralized mechanism for handling and disseminating new information about pesticides could help alleviate this problem.

7. *A mechanism should be established for restricting use of a registered pesticide temporarily on the basis of information*

which implicates the chemical as a possible health hazard pending the collection of more definitive information.

If a pesticide is already in established use, the decision is particularly difficult. Long established use inevitably implies a dependence upon it by the consumer and a corresponding reluctance by the manufacturer to withdraw it from the market.

At the present time, a registration may be held in abeyance only by cancellation or suspension. Because of the serious import of these actions they are put into effect with considerable reluctance. They were not designed for situations such as the present with respect to 2,4,5-T where temporary withdrawal from use, without cancellation or suspension of registration, might have been a more appropriate

[p. 5]

action. Such an alternative course of action is not possible under present regulations.

There is need for a mechanism whereby the use of a pesticide or other chemical that may affect human health can be temporarily restricted or held in abeyance. Such action would permit the gathering of more definitive information in time for sufficient consultation to permit a decision that would protect the public health and not impose an undue economic burden on the producers, marketers, and users of a product. Coincident with the imposition of restrictions on a pesticide, a mechanism should be available for informing and educating pesticide users and applicators so as to make them more responsible agents. It is recognized that a change in the law governing pesticides would be necessary to accommodate this mechanism of a temporary restriction.

8. *There is an urgent need for a focus of responsibility in D/HEW to coordinate and monitor the toxicity and health activities related to effects of pesticides.*

Information about the health effects of a pesticide derives from a variety of sources including occupational exposures, residue monitoring, toxicological investigations, clinical experience and epidemiological studies. In the past, there has been no single focus within D/HEW which has been concerned with all of these sources of data and, more important, which has had the authority and responsibility to coordinate new investigative initiatives. The new Advisory Committee on Pesticides to the Secretary of D/HEW can be expected to serve as a source of expert advice but cannot fill the essential need for a focus of responsibility and authority at the level of the Office of the Secretary. Consideration of the functions to be fulfilled and the resources available suggests that this responsibility should be assigned to the Assistant Secretary for Health and Scientific Affairs because the various components of D/HEW concerned most with aspects of the health effects of pesticides report directly to him (National Institutes of Health, Food and Drug Administration, National Communicable Disease Center, Environmental Health Service).*

9. *Information provided in applications for registrations of pesticides should take into account not only the pesticide for which registration is sought but should identify other substances including vehicles used in formulations, "inert" ingredients, and impurities.*

Investigation of the synthesis of 2,4,5-T and examination of the manufacturing process revealed that an extremely toxic impurity, 2,3,7,8-tetrachlorodibenzo-p-dioxin, present in variable amounts in

[p. 6]

commercial preparations of 2,4,5-T, may account for some of the toxicological characteristics assigned to 2,4,5-T itself. The presence of this impurity was recognized as early as 1957. However, the importance of this impurity was not generally recognized in the United States until after 1964. It appears logical that greater specificity in identifying the components and properties of the mixture of materials which are registered under a single name would increase the probability of identification of potentially toxic substances.

10. *Registration procedures should be based on toxicological studies of the particular compounds to be registered rather than extrapolations from studies on related compounds.*

Toxicological studies provided as information in behalf of 2,4,5-T registration were performed on a variety of related compounds (the free acid, several types of esters and a variety of salts). Results of these tests were regarded as being interchangeable and applicable to the related compounds. There is evidence to caution against this concept. The thorough testing of isomers, esters, salts, and related compounds is a very large and expensive task. Nevertheless, information about a potential health hazard may be incomplete unless all of the compounds to be used are tested.

[p. 7]

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* Since this report was written, the President established, through Reorganization Plan, the Environmental Protection Agency which is to be responsible for broad areas of regulation covering environmental matters. The Environmental Protection Agency will also have the capacity to carry out some research under its name. Hence, we recognize that some of the elements of coordination recommended in this section will be accommodated by this new agency.

INTRODUCTION

In 1964, The National Cancer Institute undertook through a contract a screening study of a number of pesticidal chemicals. Among the results of this screening study was the finding that birth defects could be provoked experimentally in rats and mice by the administration of relatively large doses of the herbicide, 2,4,5-T. By the time these results were reported, 2,4,5-T had been in common use as an herbicide for more than 20 years. Further, it had been employed along with 2,4-D as a defoliant in Vietnam since 1962, although in sizeable quantities only since 1967.

In October 1969 several agencies of Government moved in a coordinated manner to bring about restriction of the use of 2,4,5-T both within the United States and abroad *(1)*. In terms of domestic agricultural use, restriction was placed on the use of 2,4,5-T on food crops pending the acquisition of further information that might permit the Food and Drug Administration to grant a tolerance. Use as a defoliant in Vietnam was restricted to non-populated areas.

For a number of reasons, it seemed wise to explore this issue in some detail. The most important of these reasons, perhaps, was the desire to examine the scientific evidence available to stand behind future policies governing the use of 2,4,5-T and to suggest directions for further experimental research. Accordingly, a panel of experts was assembled by the President's Science Adviser to consider a number of aspects of a variety of herbicides some of which where used as defoliants in Vietnam. The present report represents their review of 2,4,5-T.

This review considers topics which are of concern to those who are faced with policy decisions for 2,4,5-T. We hope that it can serve as an example for the consideration of the health effects and safety of pesticides and other chemicals purposefully placed in the environment.

A number of issues are raised when the utility and safety of an already existing material is questioned. It is elementary but nevertheless true to say that the issues are complex. In a way, their examination can be compared to following a seemingly endless and continuously branching program. The subject of how much assurance of safety should be afforded is important.

Teratogenesis appears to be a more manageable problem than some other health effects (such as tumor production). Prediction of [p. 8] safety can probably be made with reasonable assurance. In addition, experiments to test a suspected substance are reasonably straightforward to conduct.

Among other problems, the purity of the chemical became an issue. In the case of 2,4,5-T separation of biological effects of the principal material from those of the impurities turned out to have unusual importance. For this reason, the resolution and accuracy of analytic methods available and used to detect 2,4,5-T and its impurities had to be evaluated. In ascertaining the probable hazard to man of an agricultural chemical, its toxicity in absolute terms must be related to the probabilities of human exposure. Residue information on 2,4,5-T therefore was explored.

Finally, there remains a series of policy questions which are at least as philosophical as they are technical, the most crucial one being how wide a margin of safety should a society adopt for itself.

The panel also touched on a narrower aspect of this question by posing an additional one. This is the practical problem, in the case of a material already in use, of how the Government should act in the interim between the time of acquisition of preliminary experimental data which reveal a chemical suspect and the performance of more definitive experiments which establish the risk.

REFERENCES

(1) Press Release on 2,4,5-T. Office of Science and Technology, October 29, 1969.

[p. 9]

CHEMISTRY

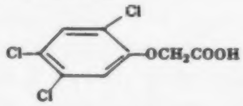
SUMMARY

2,4,5-trichlorophenoxyacetic acid is produced commercially by a process which begins with tetrachlorobenzene as starting material. Technical grade 2,4,5-T is 90–92% pure acid. One of the important impurities, a polychlorinated dioxin, results both from impurities in the starting material and as side products of the desired reaction. A large number of esters and amine salts of 2,4,5-T have been developed as well as a variety of formulations in order to derive specific properties of volatility and solubility. About one-half of this total production can be accounted for by the 2,4,5-T acid and its n–butyl ester. The free acid is practically insoluble in water and, generally, the esters are slightly soluble. The amine salts tend to be more soluble. Among other things, penetration into the soil or leaching is a function of water solubility.

In general, 2,4,5-T residues can be expected to be relatively unstable materials in the environment. They are broken down by microbial action and by sunlight and esters are readily hydrolyzed to the free acid. Available analytic methods for detecting residues are quite sensitive. The sensitivity of gas chromatography with microcoulometric detection is about 0.01 ppm (10 ppb). Detection of residues in plant material appears to be uncomplicated by bound or complexed residues with the possible exception of residues in the peels of citrus fruits.

CHEMICAL SYNTHESIS OF 2,4,5-T

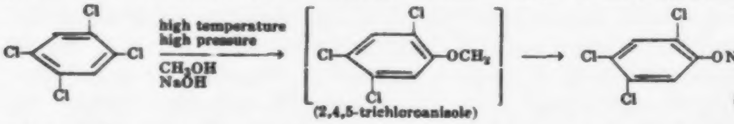
The herbicide commonly known as 2,4,5-T or 2,4,5-trichlorophenoxyacetic acid has the chemical formula:


Cl
Cl
OCH₂COOH
Cl

The usual starting material in the chemical synthesis of 2,4,5-T is 1,2,4,5-tetrachlorobenzene which can be reacted with methanol

[p. 10]

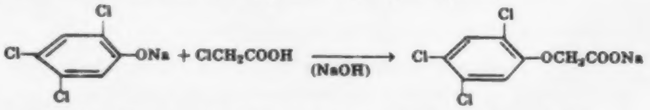
and sodium hydroxide in an autoclave under high temperature and pressure conditions to give the sodium salt of 2,4,5-trichlorophenol:


Cl
Cl
Cl
Cl
high temperature
high pressure
CH₃OH
NaOH
Cl
Cl
OCH₃
Cl
(2,4,5-trichloroanisole)
Cl
Cl
ONa
Cl

[1]

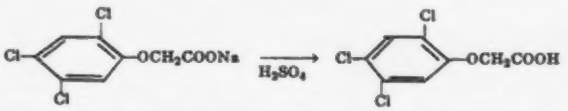
2,4,5-trichloroanisole is presumed to be an intermediate in this reaction. The high temperature and high pressure conditions of this step are also favorable for the production of a variety of other compounds from these starting materials. The choice of the proper temperature and pressure, and the control of these conditions throughout the reaction are critical for minimizing side reactions and hence impurities in the final product.

The aqueous trichlorosodium phenoxide is next reacted with chloroacetic acid under mildly alkaline conditions.


Cl
Cl
ONa + ClCH₂COOH
Cl
(NaOH)
Cl
Cl
OCH₂COONa
Cl

[2]

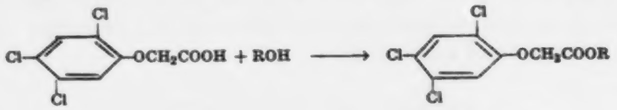
This product is then acidified with H_2SO_4 to produce 2,4,5-T.


Cl
Cl
OCH₂COONa
Cl
H₂SO₄
Cl
Cl
OCH₂COOH
Cl

[3]

The conditions for reactions [2] and [3] are mild compared with those required for the hydrolysis in step [1].

The acid reacts readily with a variety of alcohols to produce a large selection of esters, and with amines to produce amine salts.



COMMERCIAL FORMULATIONS OF 2,4,5-T

The 2,4,5-T compounds used in commercial spray formulations include the acid, salts, and a wide variety of esters and mixtures of esters. These active components are then formulated with solvents and other ingredients to produce a bewildering array of commercial final products marketed under cryptic trade names.

2,4,5-T formulations are applied as solids or liquids. The solids usually involve 2,4,5-T esters incorporated with clays, talcs, Fullers

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earth, mineral silicates, or fertilizers. One of the major hazards in the use of 2,4,5-T is drift of the herbicide into areas where it is not desired due to volatility of the formulation or drift of fine particles in the wind. This hazard is reduced in one solid formulation for which the active material is deposited on polystyrene spheres with a very narrow and carefully controlled particle size distribution.

The liquid formulations require a solvent. Typical organic solvents are kerosene or diesel oil. In formulations that are mixed with water for spraying, emulsifiers and surfactants are necessary ingredients. A truly thorough attempt at estimation of the toxicity of the several commercial preparations of 2,4,5-T should take into account all of the added material, "inert" ingredients, vehicles and impurities.

2,4,5-T is most commonly employed as an ester or amine salt (Table 1). The n–butyl ester is used as a defoliant in Vietnam in a 1:1 mixture with 2,4-D, known as Orange.

TABLE 1.—PRODUCTION AND VALUE PER POUND OF MAJOR 2,4,5-T FORMULATIONS—1967

[Drawn from U.S. Tariff Commission, 24]

	Production (1000 lbs.)	Unit value per pound ($)
2,4,5-Trichlorophenoxy-acetic acid (2,4,5-T)	14,552	1.25
2,4,5-Trichlorophenoxy-acetic acid esters and salts, total	27,189	0.80
2,4,5-Trichlornphenoxy-acetic acid, n-butyl ester	19,422	0.68
2,4,5-Trichlorophenoxy-acetic acid, iso-octyl ester	4,653	1.16
All other (2,4,5-T esters and salts)	3,114	1.09

SOLUBILITIES

The solubility of the herbicide compound used may be important in determining the mechanism by which the toxic material enters the plant. It also determines the nature of the vehicle to be used in its dispersion.

The free acid form of 2,4,5-T is practically insoluble in water *(8)*. The sodium salt is only soluble to a limited extent (less than 3%), a fact which precludes its use in the low volume application technique which has become more and more widely used in recent years.

The amine salts are considerably more soluble in water; however, they are somewhat difficult to prepare. Only the triethyl and trimethylamine salts can be obtained in a concentrate of 4 lbs. acid equivalent/gal. with satisfactory storage qualities. Furthermore, the marked insolubility of the calcium and magnesium salts of 2,4,5-T which are formed upon dilution with water causes nozzle clogging during application. Therefore, these formulations are not widely used. Ester formulations are most commonly used as oil-water emulsions.

The extent of leaching of various herbicide formulations was tested by applying these in solution to the tops of soil containing tubes. The depth of leaching could in general be compared with solubility. For

[p. 12]

example, the amine salt of 2,4,5-T was taken to a depth of nine inches whereas 2,4,5-T itself remains at three inches.

Aside from the herbicide itself, leaching of diesel oil, a vehicle commonly used in herbicide application, might present a threat to ground water quality. However, Lindin and Muller (cited in *13*) sprayed diesel oil at rates of 50, 250, and 500 gal./acre, and after sampling with a tube and leaching with rain water, they found only 1.5–2 ppm of diesel oil in sandy loam above 2.5 inches.

TABLE 2.—2,4,5-T PRODUCT COMPOSITION

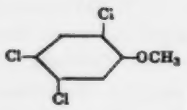
Percent by weight:	
91.0±1.0	2,4,5-trichlorophenoxyacetic acid
0.5±0.1	2,4,5-trichloroanisole
2.0±0.5	5-methoxy 2,4-dichlorophenoxyacetic acid
2.0±0.5	2-methoxy 4,5-dichlorophenoxyacetic acid
0.3±0.1	2,4,5-trichlorophenol
3.0±0.5	bis-2,4,5-trichlorophenoxyacetic acid
0.3±0.1	2,5-dichlorophenoxyacetic acid
0.2±0.1	SO_4
0.2±0.1	Sodium salt of 2,4,5-T
0.5±0.2	N_2O
less than 1 ppm tetrachlorodibenz-p-dioxin (TDD).	

PURITY OF TECHNICAL GRADE MATERIAL

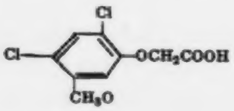
Technical grade 2,4,5-T manufactured for agricultural applications typically contains 90 to 92% 2,4,5-trichlorophenoxyacetic acid, and 8 to 10% impurities. The detailed composition of the technical material given by one producer is shown in Table 3.

The 1,2,4,5-tetrachlorobenzene starting material for the 2,4,5-T synthesis contains typically 3% other tetrachlorobenzene isomers and other chlorinated benzenes. These impurities can contribute to small amounts of a variety of other chlorinated products including dichlorophenoxyacetic acids and other isomers of the trichlorophenoxyacetic acid, although these products were not listed by the manufacturer as impurities (Table 3).

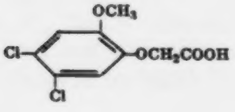
2,4,5-trichloroanisole,



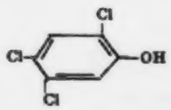
is proposed as an intermediate in step (1) of the manufacturing process. Incomplete reaction of this intermediate accounts for its presence in the final product. There is also a possibility that the 2,4,5-trichloroanisole intermediate can be hydrolyzed under the conditions of step (1) to give methoxydichlorophenoxyacetic acid as side products:



[p. 13]

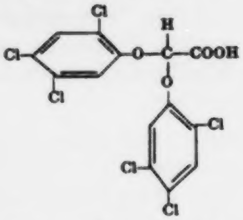


and 2,4,5-trichlorophenol,



results from the incomplete condensation of the sodium phenoxide with chloroacetic acid in step (2).

Bis-2,4,5-trichlorophenoxyacetic acid,



is an important impurity because the chloroacetic acid used in step (2) commonly contains some dichloroacetic acid. The 2,5-dichlorophenoxyacetic acid arises from small amounts of 1,2,5-trichlorobenzene in the tetrachlorobenzene raw material. Some sodium 2,4,5-T and sulfate ions are commonly carried into the product from the acidification (step [3]).

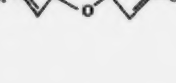
The standard assay for technical grade 2,4,5-T is a simple titration to give the acid equivalent of the product. On this basis most manufacturers market a product that has 97 to 98% acid equivalent. Analysis for actual 2,4,5-trichlorophenoxyacetic acid content by gas chromatography is less commonly given, although a standard method exists. The Department of Agriculture reported that the content of 2,4,5-T was often as low as 85% in commercial materials that meet the 97% acid equivalent specification. *(22)* Gas chromatography is used to monitor trace impurities in process control for step (1).

The impurities present in any commercial preparation of 2,4,5-T depend strongly on the purity of the starting materials and the reaction conditions. These can vary among various producers and among batches for a given producer.

The detailed processing methods and purification procedures also vary widely among the various producers. The variation in product analysis has not been carefully documented, and the toxicities of most of the impurities have not been tested. It is not prudent to assume that the combined toxicity of the mixture of materials in one preparation is representative of all of the preparations that are widely used.

[p. 14]

One trace impurity produced in the manufacture of 2,4,5-T has received considerable attention. Tetrachlorodibenz-p-dioxin, commonly known as TDD,

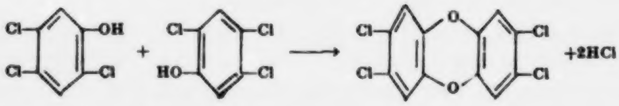


is produced as a side product under the conditions of step (1). Since this compound is known to be extraordinarily toxic, the history of the recognition and identification of this impurity is particularly interesting. Elucidation seems to have come from two principal independent sources.

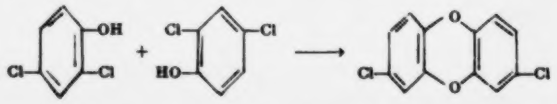
The sporadic occurrence of an impurity in specific lots of animal feed in 1957 brought significant losses to poultry farmers in southeastern and central U.S. Chicks were afflicted with hydropericardium, and suffered gross kidney and liver damage. Empirical tests for the presence of the "chick edema factor" were announced by the FDA in 1966 *(11)*. The test used electron capture gas chromatography to examine a fraction of a sample isolated from the fat. The presence of a specific set of peaks with given retention times indicated the presence of the factor. The empirical test is used as a screening procedure. When the presence of the factor is indicated by gas chromatography, a chick bioassay test is required for confirmation. The absence of the factor is a requirement of the edible tallow used for making fatty acids that go into food emulsifiers.

The chick edema factor was identified by X-ray crystallography as 1,2,3,7,8,9-hexachlorodibenz-p-dioxin in 1967 by Wootton of Proctor and Gamble *(25)* from 4 mg of toxic material extracted from 100 lbs. of contaminated fat obtained from trade sources. The toxicity of this compound and related compounds was reported by representatives of the Food and Drug Administration in 1968 *(11)*.

A clue to the possible origin of the dioxins was suggested in their synthesis by condensation *(21)*. Two molecules of 2,4,5-trichlorophenol condense directly to give TDD:



Two molecules of 2,4-dichlorophenol condense to give the dichlorodibenz-p-dioxin,



and mixtures of various isomeric chlorinated phenols give mixed chlorinated dioxins.

[p. 15]

The FDA group reported the following toxicities:

TABLE 3.—AFTER HIGGINBOTHAN, ET AL. (12)

Reactants	No. of Cl atoms in dioxin	Chicken embryo bioassay	
		µg/egg	percent mortality
2,4-dichlorophenol	2	500	70
Chlorinated dibenz-p-dioxin[1]		0.05	100
2,4,5-trichlorophenol	4	0.25	100
2,4,6-trichlorophenol	4	5.0	50
2,3,4,6-tetrachlorophenol	6	1.0	100
Pentachlorophenol	8	5.0	27
Reference toxic fat components	Mixture	3.0	100

[1] Mixed 3 and 4 chloro species.

The tetrachloro species, which will be the important product from the condensation of 2,4,5-trichlorophenol, requires only 0.25 µg for 100% mortality in the chick embryo bioassay. A mixture of the tri- and tetrachloro species was reported in one study to be more toxic than the tetrachloro species alone (*12*). However, more recent unpublished observations by the same authors have pointed toward a singularly high degree of toxicity of the four chlorine members of the family. The conditions required for the production of the tetrachlorodibenz-p-dioxin, TDD, are present in step (1) of the commercial 2,4,5-T synthesis, so this material can be present in the original herbicide. Members of the family of dioxins have been recognized in a variety of environmental situations. The origins of these are not clear in every case (*23*).

The second source of information about the toxicity of dioxin compounds came from observations of occupational exposures in plants manufacturing 2,4,5-T. These are reviewed in another section of this report. One of the diseases reported was a particularly refractory form of skin rash known as chloracne. This was also seen in workers involved in the production of other compounds. The first report of chloracne in 2,4,5-T plant workers was in 1957 (*14*). The authors in this case suggested that the dioxin impurity may have been the factor which caused the chloracne.

In 1964, the Dow Chemical Company (*6*) attempted to increase the production of 2,4,5-T by changing the reaction conditions. Plant operators became affected with chloracne. The Dow Chemical Company closed their facility and, early in 1965, alerted other manufacturers of their problem. The active agent was identified as 2,3,7,8-tetrachlorodibenz-p-dioxin. In addition, an analytical method for its detection was standardized and various methods for removing the impurity were devised. By 1965, sufficient technology was available to allow the manufacture of

2,4,5-T and 2,4,5-trichlorophenol containing no more than 1 ppm of 2,3,7,8-tetrachlorodibenz-p-dioxin. By 1966, a new Dow plant, conforming to those specifications, was

[p. 16]

put into operation. TDD levels in technical grade 2,4,5-T from another manufacturer are listed year by year in Table 4. Dioxin levels in 2,4,5-T currently manufactured are reported not to exceed 1 ppm.

TABLE 4.—HISTORY OF TDD CONCENTRATION IN TECHNICAL 2,4,5-T

[Analysis of material from one manufacturer]

Date	ppm, TDD
1958	11
1959	11
1960	8
1961	5
1962	10
1963	11
1964	12
1965	5–32
1966	3–18
1967	1–25
1968	1–25
1969	<1

ANALYTICAL METHODS

1. *Standard Procedures.*

A typical method for the analysis of herbicide residues in oil seed crops has been described by G. Yip of the FDA *(27)*. The method involves extraction of 50 grams of oil with sodium bicarbonate solution, acidification, and extraction of the herbicides with chloroform. The herbicide residues in the acid form are then esterified with diazomethane to produce the methyl esters which are finally analyzed by programmed temperature gas chromatography. Both electron capture and microcoulometric detection schemes are used. The microcoulometric detector consists of a quartz tube condensation chamber where the herbicide is pyrolyzed at 800° C in the presence of oxygen. The HCl formed is carried into a microcoulometric titration cell where the chloride is titrated with silver ion. The sensitivity of this analytical scheme is about 0.01 ppm.

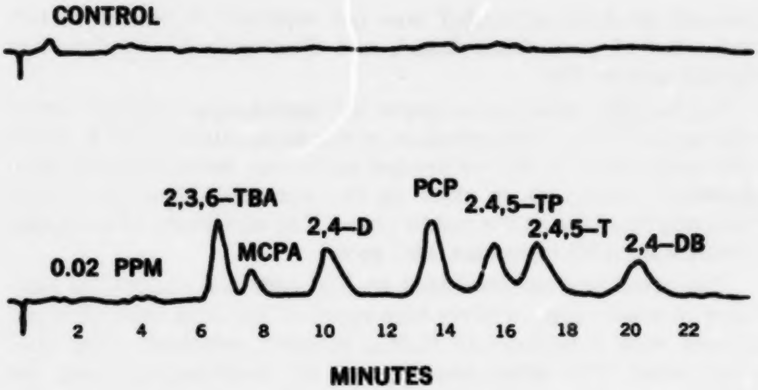
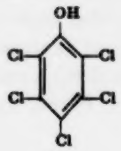
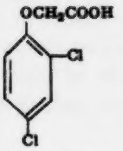


FIG. 1.—Gas chromatogram of the 0.02 ppm sample of herbicide mixture and a control. Both curves represent 35 g of cottonseed oil.—After Yip *(27)*.

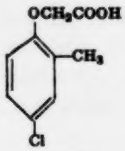
A gas chromatogram obtained from cottonseed oil treated with a mixture of seven herbicides each at 0.02 ppm is shown in Fig. 1. The seven herbicides used in this test of the method included:



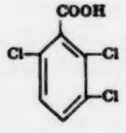
PCP



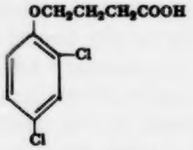
2,4-D



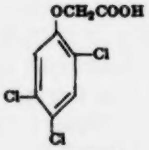
MCPA



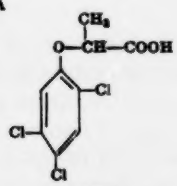
2,3,6-TBA



2,4-DB



2,4,5-T



2,4,5-TP

[p. 17]

All of these residues are well separated and readily detected after 22 minutes. Recoveries of these residues from the vegetable oil samples were better than 90% in the 0.02 to 0.08 ppm range. At the time this method was developed, samples of commercial oils including cottonseed, corn, safflower, soybean, peanut, and olive oils were analyzed for residues of these herbicides. No peaks were discerned in the chromatogram of any sample.

Although the relative retention time of 2,4,5-trichlorophenol, a common formulation impurity and one of the metabolic decom-

position products of 2,4,5-T was not reported, it should be less than that of pentachlorophenol, and thus amenable to detection by this scheme. *(9)*

Yip has also developed a paper chromatographic method which allows qualitative determination of the same esters *(28)*. A workable separation of the methylated acids was obtained using 35% dimethyl formamide in ether as the immobile phase and 2,2,4-trimethyl pentane as the mobile phase. The sensitivity of the paper chromatographic technique is 0.1 ppm.

The procedure recommended by Yip *(26)* for analysis of residues on green crops involves high speed of blending finely chopped greens with a mixture of H_2SO_4, ethanol, petroleum ether and ethyl ether. The solids are removed by centrifugation and the liquid extracted with sodium bicarbonate and chloroform, as for samples of vegetable oils. The procedure for wheat involves first grinding the wheat kernels in a mill to pass a 30-mesh screen. The ground wheat is then blended with 95% ethanol at high speed. The solids are separated by centrifugation and the residues extracted from the supernatant liquid as above.

2. *Bound Residue.* The above methods are adequate for the analysis of 2,4,5-T residues that are in the form of the free acid or various esters. The detailed analytical method provides steps for the separate examination of the residues present in free acid and ester forms although the esters are rarely found as residues in crops.

[p. 18]

An issue of primary concern, however, is whether there can exist in crops residues of 2,4,5-T chemically bound such that they are not extracted and detected by the standard analytical method. Crosby *(4)* showed that a water soluble, ether insoluble hydrolyzable form of 2,4-D is present in bean plants treated with 2,4-D. It has been reported that 2,4-D as well as other herbicides can be converted to coenzyme-A thioesters *(3)*; this is a possible form for the "bound" material. It has also been suggested that 2,4-D may be bound as 2,4-dichlorophenoxy acetylglucoside *(15)*. 2,4,5-T could presumably undergo analogous reactions to give the corresponding bound forms.

The analytical method that has been used in most plant residue studies provides no information on the fraction that may be present in bound form. In a study of 2,4-D residues in forage and milk, the residue levels shown in Tables 5 and 6 were found by the standard analytical method *(16) (29)*.

TABLE 5.—RESIDUE OF 2,4-D IN FORAGE SAMPLES FROM PASTURES SPRAYED WITH BUTYL ESTER OR 2-ETHYLHEXYL ESTER OF 2,4-D AT A RATE OF 2 LBS/ACRE. AVERAGE OF 1 TO 5 DETERMINATIONS—AFTER KLINGMAN ET AL. (16)

Date, May	2,4-D residues, ppm, from				
	Butyl ester			2-ethylhexyl ester	
	Acid	Butyl ester	Ethyl ester	Acid	Ethylhexyl ester
6[1]	0	0	0	trace	0
6[2]	58.3	0.10	0.04	36.6	11.8
8	19.2	0.18	0.02	38.6	6.7
10	9.0	0.03	0.03	23.8	2.0
13	5.0	0	0	13.7	1.4

[1] Sampled just before spraying.
[2] Sampled within ½ hr after spraying.

Residues detected by the standard method were largely in the form of the acid rather than the original esters. Some degradation of the butylester to the ethyl ester apparently occurred. Essentially no trace of residue was found in milk from dairy cows grazing in pastures sprayed with 2,4-D (Table 6).

TABLE 6.—RESIDUE OF 2,4-D IN MILK, AS DETERMINED BY TWO METHODS OF ANALYSIS, FROM DAIRY COWS GRAZING IN PASTURES SPRAYED WITH ESTERS OF 2,4-D AT 2 LB/A ON MORNING OF MAY 6, 1963. SAMPLES TAKEN FROM MORNING MILKINGS ONLY.[1]—AFTER KLINGMAN, ET AL. (16)

Date, May	Days after spraying	2,4-D residues in milk, ppm from			
		butyl ester		2-ethylhexyl ester	
		FDA	SWRI	FDA	SWRI
6	[2]0	0	0	0	0
7	1	0.01	0.01	0.01	0.03
8	2	.01	.01	.01	.02
9	3	.01	.01	.01	<.01
10	4	.01	.01	<.01	.01
11	5	.01	.01	<.01	.01
13	7	.01	.01	.01	.01

[1] Cows were kept in pastures continuously, except during milking. All data were rounded to nearest 0.01 because this is about the practical limit of precision of the methods used. FDA—Food and Drug Administration and SWRI—Southwest Research Institute.
[2] Milk was sampled in the morning before pastures were sprayed.

[p. 19]

The presence of bound 2,4-D in the grass samples from the pasture sprayed with the ethylhexyl ester of 2,4-D was also checked. To demonstrate the presence of bound 2,4-D, the acid and ester were extracted from the forage samples as usual. The filtrates were then extracted three times with ethyl ether to remove any residual 2,4-D acid and finally heated on a steam bath for 16 hours under highly acidic conditions. Presence of bound 2,4-D would be indicated if amounts of 2,4-D found in the hydrolyzates were significantly higher than those found in the filtrates before hydrolysis. Results are shown in Table 7.

TABLE 7.—PPM OF 2,4-D IN GRASS OF ETHYLHEXYL ESTER-SPRAYED PASTURE, FREE AND BOUND. (29)

Days after spraying	Initial extraction	Filtrates before hydrolysis	Hydrolyzate
Control	46	0.053	[1]
2	50	0.430	[1]
4	20	0.246	0.54
7	19	0.230	1.31

[1] Trace.

The presence of small amounts of bound 2,4-D is shown by the value obtained from the hydrolyzates. There is a trend toward increasing formation of bound 2,4-D with time. No bound residues could be detected in milk in these experiments. The results from these experiments suggest that although bound residues were detected, most of the residues were present as acid or ester and there would not have been a major discrepancy between the results of the standard method and the actual total residue concentration.

There is evidence for the binding of residues of 2,4,5-TP (Silvex), the phenoxy propionic acid analog of 2,4,5-T. A careful study of 2,4,5-TP residues in orange peel, however, suggests that a rather high percentage of the growth regulator residues can be present as insoluble "bound" materials *(10)*. 2,4,5-TP fractions could be separated on the basis of solubility into four types: free acid, ester (hexane soluble), complexed acid (water soluble, hexane soluble), and heat-labile complexed acid (heat-released). It was possible to detect the water soluble complexed acid as the methyl ester after basic hydrolysis and identification. The labile form was released after heating for 24 hours at 104–105° C. The concentrations of these various forms during a 13-week period are shown in Fig. 2.

[p. 20]

These results suggest that the original 2,4,5-TP amine salt is first converted to the free acid. This acid then is converted to a soluble conjugated form. However, it appears that the insoluble complexed form ultimately becomes a major fraction of the total residue. The results of this and other studies of herbicide residue in citrus *(7)*, *(18)* emphasize that the residues of halogenated phenoxyacetic acids may take several forms in plant tissues. Unless an effort is made to release the bound residues, the standard analytical scheme does not provide a suitable basis for estimating the total residue concentration.[*]

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[*] It is possible that only the pure acid and ester residues produce physiological effects on man and animals, while the bound forms are inert and non-toxic. The standard analytical scheme would then provide a useful measure of the effective concentration of residue in toxic form. The relative physiological effects of bound and unbound residues are unknown.

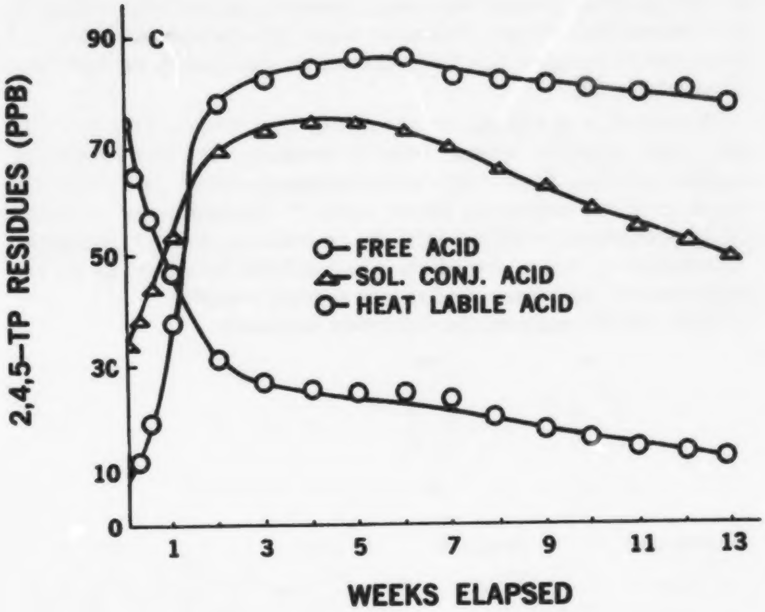

FIGURE 2.— After Hendrickson and Meaghen *(10)*.

CHEMICAL STABILITY OF 2,4,5-T

1. *Photochemical Degradation.*

Ultraviolet light has been shown to alter drastically the structure of many pesticides under laboratory conditions. Knowledge of whether sunlight under "field conditions" can also affect these transformations is critical. The detailed chemistry and toxicology of the resulting decomposition products could be significant to agriculture and the public health.

Although the photochemistry of 2,4,5-T has not been investigated, considerable effort has been expended to elucidate the pathway for photochemical decomposition of 2,4-D. It might be expected that these compounds react in a similar way. Several studies indicated that [p. 21] 2,4-D is, in fact, degraded in the presence of ultraviolet light to phenolic products *(19)*, *(1)*, *(2)*. Some evidence is available which indicates that sunlight also detoxifies 2,4-D as Penfound and Minyard *(20)* showed that malformations of water hyacinth and kidney bean plants were more severe in shaded plants than in those receiving full sun. The most recent photochemical study *(5)* is the first to compare the transformations induced by sunlight and ultraviolet light.

Photolysis in the presence of sodium bicarbonate (2×10^{-3} *M*) and water leads to several isolable products: 2,4-dichlorophenol, 4-chlorocatechol, 2-hydroxy-4-chlorophenoxy-acetic acid, and the major product, polymeric humic acids.** Although the transient 1,2,4-benzenetriol could not initially be isolated, it could be trapped if oxidation of this intermediate was inhibited by carrying out the photolysis in the presence of excess sodium bisulfite.

These results suggest the following sequence:

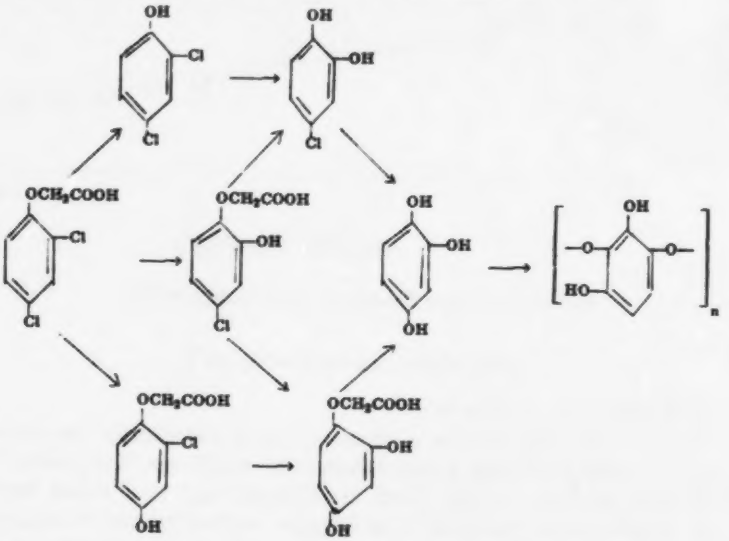

FIGURE 3. Proposed mechanism of 2,4-D photodecomposition
After Crosby *(4)*

Analogous results were obtained from irradiation in sunlight.

2. *Hydrolysis.*

The esters of 2,4,5-T are readily hydrolyzed to the free acid under acidic or basic conditions. The esters are rarely found in residues in crops. The rates of hydrolysis of course depend on the detailed stereochemistry of the ester substituent. The rate of hy-

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** No attempt was made to determine the fate of the two carbon fragment.

drolysis is reduced as the bulk of the ester group is increased close to the oxygen linkage.

[p. 22]

3. *Thermal Stability*

2,4,5-T is stable with respect to thermal degradation to at least its melting point of 153° C.

4. *Biochemical Degradation.*

2,4,5-T is slowly degraded in soil which contains organic matter under warm, moist conditions. The generally accepted half-life for this process is several weeks. However, the decay in 2,4,5-T concentration is usually not a simple first order process since the population of organisms that metabolize 2,4,5-T, increases in the presence of 2,4,5-T. In areas pre-treated with 2,4,5-T, the lifetime for degradation is significantly reduced. Three months appears to be the accepted length of time for 2,4,5-T residues in soils to disappear completely. The rate of disappearance appears to be independent of the quantity of application. Some of the organisms responsible for 2,4,5-T biodegradation have been isolated and identified. *(17)* The subject of residues is more fully examined in Section VI.

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[p. 24]

USES AND SIGNIFICANCE

SUMMARY

2,4,5-T has become important in land and waterway management. It has been very useful for brush and weed control. A result has been a growing dependence upon it. The Government itself has encouraged the use of 2,4,5-T through an agricultural cost sharing program.

Nearly 8 million acres were treated with 2,4,5-T in the United States in 1964. The major use was brush control on rangelands, pastures, and rights-of-way. Other uses were on certain food and non-food crops, in aquatic weed control and in forestry.

In 1964 and 1966 almost half of the 2,4,5-T was used on rights-of-way. Over two million acres of rights-of-way were treated in 1964 which is one quarter of the total area treated with this herbicide.

Civilian uses of 2,4,5-T dropped nearly 50% from 1964 to 1966. More recent, unpublished information from the Department of Agriculture suggests that this trend continued through 1968 but may have begun to reverse itself within the past year. This decrease accompanied price increases and shortages of supply associated with the demand for 2,4,5-T as a defoliant and tactical weapon in Vietnam. If acreage decreased proportionately, about four million acres would have been treated in 1966.

To some extent, other herbicides can be substituted for 2,4,5-T (notably 2,4-D). If all alternative herbicides were available the banning of 2,4,5-T would appear to lead to an additional cost of nearly $52 million in land and waterway management or nearly a 100% increase over the current expenditures. These figures assume practices designed to achieve the current level of management and agricultural production. If other phenoxy herbicides are also banned, the additional costs from elimination of 2,4,5-T alone would amount to $172 million or over three times the present investment. Agricultural costs are estimated to rise $32 million and $44 million, respectively, under the two assumptions, while costs of right-of-way management would rise $12 million and $75 million, respectively.

Agricultural production has become dependent upon the use of herbicides. Their use in the United States has increased rapidly during the past few years. They are employed as substitutes for the more costly practices of hoeing, cultivating, mowing, chopping, burning, and various other cultural practices for the control of weeds. [p. 25]

One of the principal uses of the herbicide, 2,4,5-T, is for control of weeds and brush on pasture and rangeland. Large quantities are also used to control brush along roadways and under powerlines. The principal crop use of 2,4,5-T is on hay and pasture.

In forest production, 2,4,5-T has proved useful for selective weed control. 2,4,5-T acts upon deciduous hardwoods leaving the conifers with little injury. This treatment has been helpful in releasing conifers from deciduous hardwood competition in mixed stands.

PRODUCTION

Total herbicide production in the United States has increased rapidly:

*1960	75,000,000 pounds *(3)*
1965	220,000,000 pounds *(8)*
1968	403,000,000 pounds *(12)*

For 2,4,5-T (acid, esters and salts), production has increased as follows:

1960	7,900,000 pounds *(7)*
1965	13,500,000 pounds *(10)*
1966	18,100,000 pounds *(10)*
1967	27,200,000 pounds *(10)*
1968	42,500,000 pounds *(12)*

A portion of this production is exported and a portion shipped abroad for military use.

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* Changes in the method of reporting after 1960 makes this figure difficult to compare with later figures.

USES

1. *Domestic.*

a. *Farm use.*

In 1964, of the estimated 13,000,000 pounds of 2,4,5-T produced in the United States, only 13 percent or about 1,655,000 pounds were used in agriculture (Table 1). About 40 percent of the quantity employed in agriculture was used for weed control along fence rows, ditch banks, farm roadways, and other noncrop uses. The remaining 60 percent or 979,000 pounds was employed on crops (including hay, pasture and rangeland).

Since 1964, the use on farms has been decreasing. In 1966, 760,000 pounds were applied which is less than 50% of the 1964 amount *(13)*. Use on hay, pasture, and rangeland declined 35 percent, and other crop use decreased by 31 percent, whereas noncrop use decreased about 84 percent.

b. *Forestry, Rights-of-way, Aquatic Weeds and Lawn and Turf.*

In 1964, about 888,000 pounds of 2,4,5-T were used in private nonfarm forest management for control of undesirable trees and brush (Table 1); in 1966, this declined to 408,000 pounds (Table 3).

TABLE 1.—ESTIMATED USE OF 2,4,5-T IN THE UNITED STATES, 1964 (13)

Use category	Land treated per 1,000 acres	Quantities of active 2,4,5-T applied per 1,000 pounds	Proportion of total quantity applied (Percent)
Farm use:[1]			
Hay, pasture, and rangeland	2,441	581	7
Other farm use	[2] 1,010	1,074	12
Total farm use	3,451	1,655	19
Non-farm use:			
Federal Government agencies[3]	296	656	7
Lawn and turf treatment[4]	1,200	600	7
Rights-of-ways[5]	2,175	4,368	49
Private non-farm forests[6]	430	888	10
Aquatic treatment[7]	81	162	2
Other uses[8]	306	583	6
Total non-farm use	4,488	7,257	81
All uses	7,939	[9] 8,912	100

[1] Based on "Quantities of Pesticides Used by Farmers in 1964," AER 131. Farm data excludes Alaska and Hawaii. In some farm uses, all acres in a field were reported treated while only spots actually received 2,4,5-T, thus making the rate per acre seem low.

[2] Sum of the acres of all crops, except hay, pasture, and rangeland treated, plus an acreage estimate for noncropland receiving treatment. The acreage of noncropland was estimated by allocating the quantity of 2,4,5-T used for such purposes at the rate of 2 pounds per acre.

[3] Based on 1969 usage of the Departments of Agriculture, Interior, and Defense; and 1951–69 average usage by the Tennessee Valley Authority.

[4] Based on estimated 500,000 acres of turf and 700,000 acres of lawns treated. Estimates based on "Extent and Cost of Weed Control with Herbicides and an Evaluation of Important Weeds," ARS 34–102; and unpublished data.

[5] Based on sources cited in footnote 4 with rate of application same as for federally treated rights-of-way. Does not include rights-of-way treated by Federal agencies.

[6] Estimated at 4 times the acreage treated and quantities of pesticides applied to public forests.

[7] Based on sources cited in footnote 4 and rates used on federally treated waterways.

[8] Includes governments other than federal and any other usage.

[9] Based on table 28 of the Pesticide Review 1969, Ag. Cons. Stab. Service.

An estimated 4,368,000 pounds were applied to rights-of-way, roadways, fire lanes, and similar areas for tree and brush control in [p. 26] 1964 (Table 1); in 1966, this had decreased to 2,315,000 pounds (Table 3).

About 162,000 pounds were applied to aquatic habitats in 1964 for weed control on about 81,000 acres (Table 1); in 1966, this had dropped to 75,000 pounds (Table 3).

TABLE 2.—FARM USE OF 2,4,5-T ON CROPS, BY CATEGORY OF USE, UNITED STATES, 1964 AND 1966 (13)[1]

Use category	Active ingredients per 1,000 pounds		Acres treated per 1,000 acres		Percentage of planted acres treated with 2,4,5-T (percent)	
	1964[2]	1966[3]	1964[2]	1966[3]	1964[4]	1966[5]
Hay, pasture, and rangeland	581	379	2,441	861	0.4	0.1
Corn	72	58	255	337	0.4	0.5
Wheat	16	26	55	59	(6)	0.1
Sorghum	5	6	48	18	0.3	0.1
Rice	(7)	23	(7)	16	(7)	0.8
Other grains	264	34	196	99	0.4	0.2
Other crops	41	127	117	175	0.1	0.2
All crop usage	979	653	3,112	1,565	0.3	0.2

[1] Does not include Alaska and Hawaii. Use in 1964 generally reflects current practices. Use in 1966 was unusually small and not representative of current practices because of domestic shortages due to increased military purchases.

[2] Revised estimates based on Quantities of Pesticides Used by Farmers in 1964. U.S. Dept. Agr., Agr. Econ. Rpt. No. 131, Jan. 1968.

[3] Data from the ERS Pesticide and General Farm Survey, 1966.

[4] Acres treated as a percent of acres grown as reported in Stat. Bul. 384 and Agricultural Statistics 1968.

[5] Acres treated as a percent of acres grown as reported in Crop Production, 1967. U.S. Dept. Agr., Cr. Pr. 2-2(7-67).

[6] Less than one-tenth percent.

[7] Included in other grains in 1964 only.

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TABLE 3.—QUANTITIES OF 2,4,5-T USED AND PERCENTAGE CHANGE IN USE, UNITED STATES, 1964 AND 1966 (13)

Use category	Quantities of active 2,4,5-T applied per 1,000 pounds		Reduction from 1964 usage in percent
	1964[1]	1966[2]	
Farm use:[1]			
Hay, pasture, and rangeland	581	[2]379	35
Other farm use	1,074	[2]381	65
Total farm use	1,655	[2]760	54
Nonfarm use:			
Federal Government agencies	656	[3]450	31
Lawn and turf treatment	600	[4]300	50
Rights-of-way	4,368	[5]2,315	47
Private nonfarm forests	888	[6]408	54
Aquatic treatment	162	[7]75	46
Other uses	583	[8]292	50
Total nonfarm uses	7,257	3,840	48
All uses[9]	8,912	[9]4,600	48

[1] See table 1.

[2] Data from 1966 ERS Pesticide and General Farm Survey, U.S. Dept. of Agric.

[3] Based on decreases in Forest Service spending on timber improvement, and cooperative programs with states.

[4] Assuming 50 percent shift to dicamba.

[5] Residual after providing for other requirements.

[6] Based on same rate of reduction as total farm use.

[7] Based on same rate of reduction in 2,4,5-T use on hay, pasture, and rangeland.

[8] Assuming 50 percent of the 1964 use of 2,4,5-T was retained.

[9] Based on tables 2 and 3.

About 600,000 pounds of 2,4,5-T were applied to lawns and turf in 1964 (Table 1); in 1966 this had fallen to 300,000 pounds (Table 3).

c. *Fruit.*

Small quantities (less than 10,000 pounds) of 2,4,5-T were used as a growth regulator to thin fruit in the spring and hold it on the tree until harvest in the fall *(9)*.

d. *Federal Agencies.*

The DOD, USDI, and USDA are the chief Federal agencies that use 2,4,5-T on the lands they manage. During 1964 in continental United States the Federal agencies used a total 656,000 pounds (Table 1).

In 1969 the DOD treated 162,000 acres with 221,000 pounds of 2,4,5-T in continental United States *(16)*. The majority of that used by the Department of Defense was by the U.S. Army Corps of Engineers Civil Works Program for the control of aquatic weeds in navigable waters, in and around reservoirs, on stream banks and rights-of-way. The use of herbicides on DOD installations is generally restricted to small areas such as training sites, lawns, fringes of air fields, fence rows and ammunition storage areas.

During 1969, the USDI treated 52,900 acres of rangeland with 38,200 pounds of 2,4,5-T; in addition 2,200 acres of aquatic habitats were treated with 5,600 pounds *(17)*.

In 1969, the USDA treated 107,000 acres of timberland with 221,000 pounds of 2,4,5-T. In addition, 34,000 acres of rangeland and [p. 28] 2,000 acres of rights-of-way were treated with 94,000 pounds (unpublished figures).

e. *Economic Importance.*

It is estimated that herbicides contribute significantly to the profits of agriculture. For example, if phenoxy herbicides (including 2,4,5-T) were not available, the net loss to rice producers in the United States has been estimated at $7.6 million per year. This represents some 2% of the farm value of all of the rice produced in the United States per year or about 25% of the value of production from acres treated with phenoxy herbicides *(13)*.

2,4,5-T has a major use for control of brush under transmission lines. It is estimated *(13)* that the control of brush with 2,4,5-T on rights-of-way costs about $6.50/acre. Other chemicals which could be substituted for 2,4,5-T on most of this acreage would cost $42/acre. Manual control costs about $44/acre.

The loss to agriculture if 2,4,5-T were no longer available would be about $32 million (based on normal use in 1964 (see Table 4)). Because of military demands for 2,4,5-T in Vietnam, the quantity used in agriculture has declined by about one-half (Table 3).

It has been estimated that the increased costs of alternatives for 2,4,5-T for nonfarm use were about $20 million for 1964 (Table 4). Between 1964 and 1966 these uses were also cut in half (Table 3).

If 2,4,5-T were not available and other phenoxy herbicides could not be used as alternatives, it is estimated that the domestic cost would be approximately $172 million (about $44 million for farm use and $128 million for nonfarm use (Table 5)).

f. *Registered Uses.*

The registered uses of 2,4,5-T are shown in Table 6 for food-crop use and in Table 7 for non-food crop use *(14)*. [p. 29]

TABLE 4.—ECONOMIC EFFECTS OF BANNING 2,4,5-T, IF OTHER PHENOXY HERBICIDES AND ALL OTHER REGISTERED HERBICIDES COULD HAVE BEEN USED, UNITED STATES, 1970 (13)

Use category	Estimated acres treated with 2,4,5-T[1]	Acres that could be treated with alternative	Acres requiring additional cultural practices	Cost of 2,4,5-T and application	Cost of alternative herbicides and application	Cost of additional cultural practices	Net increased cost of using alternative[2]
	1,000 acres	1,000 acres	1,000 acres	1,000 dollars	1,000 dollars	1,000 dollars	1,000 dollars
Farm use:							
Hay, pasture, rangeland [3]	2,441	488	1,953	4,052	1,781	32,443	30,172
Other farm use[4]	1,010	879	774	3,968	3,245	2,486	1,763
Total farm use	3,451	1,367	2,727	8,020	5,026	34,929	31,935
Nonfarm use:							
Federal Government[5]	296	281	15	3,287	3,765	735	1,213
Lawn and turf[6]	1,200	1,200	60	2,850	3,720	240	1,110
Rights-of-way[7,8]	2,175	1,958	217	33,772	36,028	9,548	11,804
Private nonfarm forests[7,9]	430	387	43	3,738	4,411	3,363	4,036
Aquatic areas[7,10]	81	72	8	608	760	240	392
Other[11]	306	291	15	2,219	3,026	375	1,182
Total nonfarm use	4,488	4,190	358	46,474	51,710	14,501	19,737
Total all uses	7,939	5,557	3,085	54,494	56,736	49,430	51,672

[1] From Table 1.

[2] Cost of alternative herbicides and application plus cost of additional cultural practices less cost of 2,4,5-T and application.

[3] The alternative herbicide was 0.5 lbs. silvex and 1 lb. 2,4-D on 20% of the acres treated. Cultural treatments on the other 1,953,000 acres include renovating a third of the acres at $15.66 an acre; then bulldozing 72% of the remaining two-thirds at $23.16 an acre, and mowing the other 28% at $1.50 an acre.

[4] Most acres of individual crops treated with 2,4,5-T in 1964 could have been treated with 2,4-D. Silvex was applied with 2,4-D on the noncropland. Rates of 2,4-D use on crops were assumed to be the 1966 average rate of all phenoxy usage for that crop except for other grains where 2,4-D was used at the same rate as 2,4,5-T. Supplemental hand or mechanical control was used on some of the corn, sorghum, and noncropland. Additional acres of wheat, other small grains, and other crops were grown to maintain production in spite of yield losses. In rice production, additional fertilizer and a change in the crop rotation were required to maintain production and offset loss in quality.

[5] Based on 1968 use by the Departments of Agriculture, Interior, and Defense; and TVA. Two lbs. each of 2,4-D and silvex were substituted for 2,4,5-T on 95% of all acres treated in 1964. Remaining acres required additional cultural, mechanical, and manual controls averaging $49.00 per treated acre.

[6] All acres could have been treated with 0.5 lbs. each of 2,4-D and silvex, but $4.00 of manual work was also required on 5% of all acres.

[7] Two lbs. each of 2,4-D and silvex were used as substitutes for 2,4,5-T on 90% of all acres.

[8] Ten percent of the acres required hand cutting at $44.00 per acre.

[9] Ten percent of the acres were mowed, hand cut, or undesirable species girdled at a cost of $78.21 per acre.

[10] The remainder required cleaning with a drag line at $30.00 per acre for treated acres.

[11] Two pounds each of 2,4-D and silvex were used to replace 2,4,5-T on 95% of these acres. The remaining acres required mechanical control by hand or with machines at $25.00 per acre on which used. [p. 30]

TABLE 5.—ECONOMIC EFFECTS OF BANNING 2,4,5-T IF NO OTHER PHENOXY HERBICIDES COULD HAVE BEEN USED BUT ALL OTHER REGISTERED HERBICIDES COULD HAVE BEEN USED, UNITED STATES, 1970 (13)

Use category	Estimated acres treated with 2,4,5-T[1]	Acres that could be treated with alternative	Acres requiring additional cultural practices	Cost of 2,4,5-T and application	Cost of alternative herbicides and application	Cost of additional cultural practices	Net increased cost of using alternative[2]
	1,000 acres	1,000 acres	1,000 acres	1,000 dollars	1,000 dollars	1,000 dollars	1,000 dollars
Farm use:							
Hay, pasture, and rangeland[3]	2,441		2,441	4,052		40,551	36,499
Other farm use[4]	1,010	628	618	3,968	6,386	5,167	7,585
Total farm use	3,451	628	3,059	8,020	6,386	45,718	44,084
Nonfarm use:							
Federal Government[5]	296	83	213	3,287	3,901	10,863	11,477
Lawn and turf[6]	1,200	1,200	1,200	2,850	2,310	4,800	4,260
Rights-of-way[7]	2,175	1,631	544	33,772	84,812	23,936	74,976
Private nonfarm forests[8]	430		430	3,738		33,630	29,892
Aquatic areas[9]	81		81	608		2,430	1,822
Other[10]	306		306	2,219		7,650	5,431
Total nonfarm use	4,488	2,914	2,774	46,474	91,023	83,309	127,858
Total all uses	7,939	3,542	5,833	54,494	97,409	129,027	171,942

[1] From Table 1.

[2] Cost of alternative herbicides and application plus cost of other treatments less cost of 2,4,5-T and application.

[3] Cultural treatments include renovating a third of the acres at $15.66 an acre; then bulldozing 72% of the remaining two-thirds at $23.16 an acre, and mowing the other 28% at $1.50 an acre.

[4] Weeds on some acres of most crops treated with 2,4,5-T in 1964 could have been controlled with nonphenoxy herbicides. Important chemical substitutes used include dicamba, atrazine and oil on crops and picloram on noncropland. Supplemental hand or mechanical control was also required on some corn, sorghum, small grains, and noncropland. Additional acres of wheat, other small grains, and other crops were grown to maintain production in spite of yield losses. In rice production additional fertilizer and a change in the crop rotation were required to maintain production and offset loss in quality.

[5] Based on 1969 use by the Departments of Agriculture, Interior, and Defense; and TVA. Two pounds of picloram with a drift reducing adjuvant were substituted for 2,4,5-T on 75 percent of federally maintained rights-of-way. All other acres required cultural, mechanical, and manual control averaging $51.00 per acre.

[6] All acres can be treated with 0.5 pound dicamba but supplemental manual work costing $4.00 per acre was required on all acres.

[7] Two pounds of picloram with a drift reducing adjuvant were substituted for 2,4,5-T on 75 percent of all acres. The remainder required hand cutting at $44.00 an acre.

[8] All acres had to be mowed, hand cut, or undesirable species hand girdled at a cost of $78.21 per treated acre.

[9] All acres needed to be mechanically cleaned with a drag line at $30.00 per acre treated.

[10] All acres required mechanical control by hand or with machines at $25.00 per acre.

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USDA SUMMARY OF REGISTERED AGRICULTURAL PESTICIDE CHEMICAL USES 2,4,5-TRICHLOROPHENOXYACETIC ACID

(Principal formulations: EC esters; amine salts; Type pesticide: Herbicide and plant regulator)

Use	Tolerance (ppm)	Dosage	Limitations
		lb. actual/A.	
Pastures: Grasses	Extended	3	Heavy brush. Apply when in full leaf and after grass is well established.
		1	Light brush. Apply when leaves are fully expanded.
Rangeland clearance	Extended	4	Apply in spring by airplane when brush is in heavy foliage stage (40–90 days after leaves unfold).
Apples (McIntosh)	Extended	20 ppm spray (acid equivalent).	Preharvest drop control. Apply a single application 4–5 days before drop normally begins.
Blueberries (low bush)	Extended	1.0 (acid equivalent).	Spray on revolving cloth-covered drum held above blueberry foliage. Apply during June and July of season preceding a burn. Do not apply within 2 years of harvesting berries.
Grains, cereal (undesignated).	Extended	0.5	Apply when grain is in tiller to boot stage and weeds are in actively growing condition. Do not apply from boot to milk stage or in seedling stage.
Pastures: Grasses	Extended	3	Heavy brush. Apply when in full leaf and after grass is well established.
		1	Light brush. Apply when leaves are fully expanded.
Rangeland clearance	Extended	4	Apply in spring by airplane when brush is in heavy foliage stage (40–90 days after leaves unfold).
Rice	Extended	1.25	Apply tiller to boot and before flooding (4–8 weeks after rice emerges).
		1.5	Apply after flooding (2–3 weeks) or 7–10 weeks after planting.
Sugarcane	Extended	1	Preemergence use only (Louisiana). If cane is shaved and off-barred, treat immediately following this operation.
		4.5	Preemergence use only (Hawaii). Apply just before cane emerges.
		1	Postemergence (weeds in established cane). Apply over row when weeds are growing vigorously. Do not apply after cane is 2 feet tall.
Lakes; Ponds	Extended	4 (with 20 lbs./A. 2,4-D as ester).	Broadcast application in early spring to summer. Do not use treated water for crop irrigation or livestock drinking water.

TABLE 7.—THE NONFOOD CROP USES OF 2,4,5-T. THE DOSES LISTED BELOW ARE GIVEN IN POUNDS OF 2,4,5-T AND EQUIVALENT IN 100 GALLONS OF SPRAY USING WATER OR OIL AS THE VEHICLE. (USDA, PESTICIDE REGULATION DIVISION, AS AMENDED BY PESTICIDE REGULATION DIVISION NOTICES 70–11 (4/20/70) AND 70–13 (5/1/70).

Non-food crop uses	Pounds 2,4,5-T acid	Comment
Around farm buildings and yards	2	
Farm fence rows, lanes and roads	2–6	
Pine release in hardwood forest	2–6	
Industrial buildings including: Around factories, elevators, loading platforms, oil refineries, etc.	12–16	
Industrial sites: Airline beacon stations, airport runways, coalyards, electric transformer stations, lumberyards, parking areas, radio towers, railroad sidings, sawmills.	3–12	
Recreational areas including: Race tracks, wildlife management	5.6–10	
Rights-of-way: Fire lanes, highways, pipelines, powerlines, railroads, telephone and telegraph	4–20	
Vacant lots	2–4	

2. *Military Uses of 2,4,5-T.*

The phrase, military uses, refers to the employment of 2,4,5-T as a defoliant in operations. Basic research on herbicides proceeded through the period 1941–1947. The work was encouraged by efforts

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to develop defoliating agents for use in jungle areas of the South Pacific area during World War II *(2)*. A major demonstration of the utility of the mixture now known as Orange (1:1 mixture of the butyl esters of 2,4-D and 2,4,5-T) as a defoliant for military purposes was conducted in 1959 *(1)*.

A preliminary series of defoliation trials was conducted in Vietnam between July 1961 and April 1962 *(3)*. Operational spraying began in Vietnam in 1962 and increased sharply after 1967. Reviews on this subject are available *(3, 5, 6)*.

Two herbicide formulations used in military operations in Southeast Asia include 2,4,5-T:

Agent	Composition	Lb./Gal. of active material
Purple	n-butyl ester 2,4-D 50% (wt.). n-butyl ester 2,4,5-T 30% (wt.). Isobutyl ester 2,4,5-T 20% (wt.).	8.9
Orange	n-butyl ester 2,4-D 50% (wt.). n-butyl ester 2,4,5-T 50% (wt.).	8.9

Purple mixture was discarded early because it was found to be no more effective than Orange. Orange is applied at a rate of 24 lb. per acre from both fixed wing aircraft and helicopters. C–123 aircraft fly at 150 feet altitude at 130 knots. A swath of 240 feet per pass is sprayed. Typically, a formation of 3–9 aircraft fly at the same time.

The following table shows the total areas sprayed each year between 1962 and 1968.

TABLE 8.—LAND AREA IN VIETNAM TO WHICH DEFOLIANTS HAVE BEEN APPLIED BETWEEN 1962 AND 1968 (15)

Year	Number of acres sprayed
1962	4,940
1963	24,700
1964	83,486
1965	155,610
1966	741,247
1967	1,486,446
1968	1,267,110

It has been estimated that under usual operating conditions 90% of the released material is confined to a band about 2.0 km wide on either side of the 80 meter spray path *(15)*. This figure is based on the spectrum of particle sizes, the direction and speed of the crosswind, and the altitude. Under realistic conditions but with a crosswind at right angles to the flight path, only 0.1% of the spray would be deposited between 1 and 2 km from the center line of the flight path.

As shown in Table 8, the total area sprayed for defoliation in 1968 was less than in 1967. Defoliation was discontinued in April 1970.

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Defoliation operations have been carried out to some extent in virtually all sections of South Vietnam. The major use has been within War Zone C, War Zone D, and the Rung Sat Special Zone.

These three areas comprise about one-fifth of the total area to which defoliants have been applied.

The Rung Sat Special Zone is an area which surrounds the shipping channel into Saigon. 113,600 acres had been sprayed by the end of January 1968 *(6)*. War Zone C is northwest of Saigon between the Song Be River and the Cambodian border. 227,000 acres had been treated in War Zone C by January 1968. War Zone D, in which 405,000 acres were treated, is northeast of Saigon between the Song Be and Song Dong Hai Rivers *(6)*. Repeated application was made in some areas.

The general purposes for which defoliation operations have been used include:

a. Defoliation of lines of communication. Sites of frequent ambush have been defoliated to afford better visibility along roads and trails.

b. Defoliation of areas where Vietcong tax collectors customarily exacted payments from the populace.

c. Defoliation of enemy infiltration routes.

d. Defoliation of enemy base camps. The rationale in this case was based on the observation that the enemy tended to move out of a base after the area had been sprayed.

e. Clearing of vegetation around American base camps and fire bases in order to clear fields of fire and improve observation.

Importance of 2,4,5-T as a military defoliating agent.

Systematic studies have not been carried out to quantify the value of defoliation in Vietnam. However, many of those concerned with the program believe that the military advantages are clearly evident *(4, 15)*. The following evaluations are extracted from testimony offered by Rear Admiral W. E. Lemos before the Subcommittee on National Security Policy and Scientific Developments of the Committee on Foreign Affairs *(4)*.

a. Major defoliation has been accomplished in War Zone C. Prior to defoliation, 7 brigades were necessary to maintain US/GVN presence. After defoliation, only 3 brigades were required.

b. The Commander of Naval Forces in Vietnam in a report to General Abrams stated: "As you know, a major concern is the vegetation along the main shipping channel. Your continuing efforts under difficult and hazardous flying conditions, in keeping this area and the adjacent inland areas devoid of vegetation have contributed considerably in denying the protective cover from which to ambush the slow-moving merchant ships and U.S. Navy craft."

c. In 1968, the Commanding General of the First Field Force reported: "Defoliation has been effective in enhancing the success of [p. 34] allied combat operations. Herbicide operations using C–123 aircraft, helicopters, truck mounted and hand sprayers have become an integral part of the II CTZ operations against VC/NVA. The operations are normally limited to areas under VC/NVA control remote from population centers. The defoliation program has resulted in the reduction of enemy concealment and permitted increased use of supply routes by friendly units. Aerial surveillance of enemy areas has improved and less security forces are required to control areas of responsibility. An overall result of the herbicide program has been to increase friendly security and to assist in returning civilians to GVN control."

d. The U.S. Commander in the III CTZ related: "Herbicide operations have contributed significantly to allied combat operations in the III Corps. Defoliation is an important adjunct to target acquisition. Aerial photographs can often be taken from which interpreters can "see the ground" in areas that previously were obscured. Defoliation also aids visual reconnaissance. USAF FAC's (forward air controllers) and U.S. Army aerial observers have discovered entire VC base camps in defoliated areas that had previously been overlooked."

e. In the south in the IV CTZ, C–123 herbicide operations are limited. This is because of the vast areas of valuable crops which are not to be destroyed, even though they may be in enemy hands. Therefore, commander of the IV Corps area in presenting his evaluation cited the value of helicopter operations as follows: "A significant helicopter defoliation mission was conducted in the vicinity of SADEC in August 1968. The target area consisted of 3 main canals which converged and formed a strong VC base. The dense vegetation permitted visibility of only 10–15 meters horizontally and nil vertically. The area was sprayed with approximately 135 gallons of herbicide White and over 90 percent of the area was defoliated. As the result of the defoliation, an ARVIN battalion was able to remain overnight in the area for the first time in five years. Many enemy bunkers were open to observation. Since the defoliation, the VC presence has decreased to the point that only RF/PF forces are now necessary for local security."

f. As a part of the 1968 evaluation report of herbicide operations, the U.S. Senior Advisor in the IV Corps Tactical Zone area reported: "A section of National Highway 4 in Phong Dinh Province was the site for a defoliation operation on 24 June 1968. Since

January 1968, a series of ambushes was conducted against SYN convoys and troop movements. Because of the total inability of ground troops to keep the area clear of VC, this area was sprayed using 685 gallons of herbicide White. The target area was primarily coconut palm and banana trees that had been abandoned by their owners for several years. During the period of abandonment the vegetation had become so dense that convoy security elements were not able to see more then five meters into the underbrush and had to rely on reconnaissance by

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fire to discover the hidden enemy. This method of protection had proven ineffective. Three RF/PF companies with U.S. advisors were used to secure the target for the helicopter operation in addition to an armord cavalry troop. Since the defoliation mission was completed, convoys have used the highway 2 or 3 times a week without attack or harassment. Only one RF platoon has remained in the area to provide local security to the hamlet and highway."

g. In certain instances, we know the VC have been forced to divert tactical units from combat missions to food-procurement operations and food transportation tasks, attesting to the effectiveness of the crop destruction program. In local areas where extensive crop destruction missions were conducted, VC/NVA defections to GVN increased as a result of low morale resulting principally from food shortages.

The most highly valued item of equipment to field commanders in Vietnam is the helicopter. There was some question when the helicopter spray equipment was first procured whether field commanders would divert the use of helicopters from combat operations for herbicide spray operations. The very fact that the commanders have used their helicopter spray equipment to the fullest and have asked for more is certainly proof that herbicide operations have been helpful in protecting the American Soldier and contributing to successful accomplishment of the ground combat mission." *(4)*

COST SHARING PROGRAMS

The Agricultural Stabilization and Conservation Service of the U.S. Department of Agriculture has provided a cost sharing program for farmers in order to encourage desirable farm and conservation practices. Included in this Agricultural Conservation Program are two programs in which 2,4,5-T was used:

1. *Control of competitive shrubs on range and pastures.*

In 1968, $7 million were paid to farmers who treated 1.9 million acres. Approximately one-half of this land was treated with chemicals, a substantial part of which was 2,4,5-T. The remainder was treated by mechanical means.

2. *Control of specified noxious weeds on farmland or biennial weeds on pasture and range lands.*

In 1968, $1.75 million were paid to farmers to treat 700,000 acres. In some cases 2,4,5-T was used, although in most cases, 2,4-D and other chemicals were employed.

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TOXICOLOGY

SUMMARY

Relatively little toxicological information has been available on 2,4,5-T. Most of the experiments prior to the National Cancer Institute screening study were of acute, single-dose or short-term toxicity. The longest period of observation was 90 days. It was assumed (not unreasonably) that the several phenoxy herbicides behaved in similar fashion toxicologically. Hence, an understanding of aspects of the toxicology of 2,4,5-T was inferred from experiments with 2,4-D. The sample sizes used in many of the early toxicity studies were so small that it is difficult to draw statistically valid inferences. The studies indicated that 2,4,5-T is only moderately toxic. Relatively little is known about the mechanisms of toxicity of 2,4,5-T or of its metabolism in man and animals.

The screening study of pesticides carried out under contract for the National Cancer Institute tested the teratogenicity of a number of compounds, including 2,4,5-T. 2,4,5-T appeared to be teratogenic in mice and rats. Subsequent studies have confirmed these observations and in addition indicated that purified 2,4,5-T containing less than 1 ppm of the toxic contaminant tetrachlorodibenz-p-dioxin as well as 2,4,5-T contaminated with 27 ppm dioxin are teratogenic. It has also been reported that dioxin by itself is teratogenic. Tumor production by 2,4,5-T was not found.

Accounts of birth defects in defoliated areas of Vietnam have been reported. The information available does not permit the conclusion that 2,4,5-T used in Vietnam has been the cause of human birth defects.

2,4,5-T is classed as a plant hormone since, in appropriate amounts, it accelerates plant growth. The mechanism of the herbicidal effect is not fully understood. However, it is generally believed that excess growth stimulation and herbicidal properties are related. Herbicidal effects occur when these materials are used in large doses.

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A. ACUTE TOXICOLOGICAL INVESTIGATIONS

Toxicological studies on 2,4-D were first reported in 1944 *(8)*. However, there were no published reports of toxicological investigations of 2,4,5-T until 1953. In that year, Drill and Hiratzka *(5)* reported a series of studies of acute and subacute toxicity of 2,4,5-T on dogs. The material used was commercially available 2,4,5-T (presumably the acid) and was administered in capsules mixed in dog food. The single acute dose ranged from 50–400 mg/kg/. Chronic toxicity was studied in this case by oral administration in doses of 2–20 mg/kg/day, 5 days per week over a period of 13 weeks. Observations and measurements made included determination of the number of days until death ensued, changes in body weight, general observations of abnormal physical signs, gross pathology of organs, and selected histology. The number of animals used was small (as few as one per dose and as many as four per dose). In brief, the findings of this study suggested that a single fatal dose for dogs lay somewhere between 100 and 400 mg/kg. It was inferred by the author that the acute LD_{50}* was around 100 mg/kg for dogs. Repeated daily doses of 20 mg/kg led to the death of all four animals tested within 11–75 days. Repeated daily doses of 10 mg/kg did not prove fatal over a 90-day period. There were some overt signs of toxicity including weight loss, stiffness of hind legs, muscular weakness and, occasionally, bleeding from gums.

The Dow Chemical Company, a manufacturer of 2,4,5-T, undertook a series of studies of acute toxicity of this material beginning around 1950. This series included a variety of species of animals and a number of the various salts and esters of 2,4,5-T and several of the various formulations. The details of these studies have never been published in the open literature. A number of them have been submitted as background material for a petition for the granting of a tolerance for the herbicide for uses of food crops. In 1954, a summary of some of this work was published by Rowe and Hymas *(17)*. Table 1 lists the various herbicidal agents tested.

Table 1. Herbicidal formulations. [p. 39]

TABLE 1.—HERBICIDAL FORMULATIONS STUDIED BY ROWE AND HYMAS (17)

Trade name	Active ingredients (percent)
2,4-Dow weed killer (formula 40)	65.0 Alkanolamine salts of 2,4-D
Esteron 44	44.0 Isopropyl ester of 2,4-D
Esteron 245 (old formulation)	33.[illegible] Isopropyl ester of 2,4,5-T: 12.1 mixed amyl esters of 2,4,5-T
Esteron 245 (present formulation)	65.3 Mono-, di-, tripropylene glycol butyl ether esters of 2,4,5-T
Esteron ten-ten	70.5 Mono-, di-, tripropylene glycol butyl ether esters of 2,4-D
Brush killer 50-50	27.2 Butyl esters of 2,4-D; 26.5 Butyl esters of 2,4,5-T
Brush killer T	52.2 Butyl esters of 2,4,5-T
Esteron 76 (used in oil solution only)	37.1 Isopropyl esters of 2,4-D; 39.0 n-Butyl ester of 2,4-D
Esteron 76E (used in either oil solution or water emulsion)	36.8 Isopropyl esters of 2,4-D; 38.8 Butyl esters of 2,4-D
Esteron brush killer (old formulation)	25.6 Isopropyl esters of 2,4-D; 24.4 Isopropyl esters of 2,4,5-T
Esteron brush killer (present formulation)	34.8 Mono-, di-, tripropylene glycol butyl ether esters or 2,4-D 33.0 Mono-, di-, tripropylene glycol butyl ether esters of 2,4,5-T
Kuron (was called H-1078)	64.5 Mono-, di-, tripropylene glycol butyl ether esters of silvex
Dow MCP amine weed killer*	69.1 Alkanolamine salts of MCP

*2-methyl-4-chlorophenoxyacetic acid.

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* LD_{50}—median lethal dose=the amount of a toxic agent which will be lethal to 50% of the test animals to which it is administered under the conditions of the experiment.

Table 2 presents a summary of the acute oral toxicities of the various herbicide components.

TABLE 2.—ACUTE ORAL TOXICITIES OF VARIOUS PHENOXY ACETATE HERBICIDAL CHEMICALS. ROWE AND HYMAS (17)

Material	Species	Sex	Vehicle	Ld.$_{50}$ (19/20 confidence limits)
				(mg./kg.)
2,4,5-T (2,4,5-Trichlorophenoxyacetic acid)	Rats	M	Olive oil	500 (391-640)
	Mice	M	Olive oil	389 (245-619)
	Guinea pigs	M and F	Olive oil	381 (307–472)
	Chicks	M and F	Olive oil	310 (211–456)
	Dogs (4)		Capsule	Range 100 (50–250)
2,4,5-T, isopropyl ester	Rats	M and F	Olive oil	495 (420–584)
	Guinea pigs	F	Olive oil	449 (362–557)
	Mice	F	Olive oil	551 (380–799)
2,4,5-T, mixed butyl esters	Rat	F	Corn oil	481 (313–739)
	Rabbit	M	Corn oil	Range 712 (500–1,000)
	Mice	F	Corn oil	940 (674–1,312)
	Guinea pigs	F	Corn oil	Range 750 (500–1,000)
2,4,5-T, mixed amyl esters	Rats	F	Olive oil	Range 750 (500–1,000)
MCP (4-chloro-o-toloxyacetic acid or 2-Methyl-4-chlorophenoxyacetic acid).	Rat	M	Corn oil	Range 700 (500–1,000)
MCP, amine salt	Rat	M	Water	Range 1,200 (1,000–2,000)
	Guinea pigs	M	Water	Range 1,200 (630–2,000)
silvex, (2[2,4,5-trichlorophenoxy] propionic acid)	Rat	M and F	Corn oil	650 (560–760)
silvex, mixed butyl esters	Rat	F	Corn oil	Range 600 (250–1,000)
	Rabbits	F	Undiluted	Range 750 (500–1,000
	Chicks	M and F	Corn oil	1,190 (707–2,000)
silvex, mono-, di-, tripropylene glycol butyl ether esters.	Rat	F	Corn oil	621 (473-814)
	Guinea pigs	M	Corn oil	Range 1,250 (500–2,000)
	Mice	F	Corn oil	Range 1,410 (1,000–2,000)
	Chicks	M and F	Corn oil	1,190 (847–1,670
	Rabbits	F	Undiluted	819 (610–1,070)

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Similarly, Rowe and Hymas reported the results of oral feeding of several commercial formulations of 2,4,5-T and related compounds (Table 3).

Rowe and Hymas concluded that the acute LD$_{50}$ for 2,4-D, 2,4,5-T, and their various formulations and combinations fell in the range of 300–1000 mg/kg. There was some variation among species with dogs appearing relatively more sensitive than other species of animals.

Military applications of 2,4,5-T as a defoliant have utilized combinations of 2,4-D and 2,4,5-T in formulations known as Orange and Purple. There has been some acute toxicological testing of the mixture, Purple, on small animals. Purple contains 50 per cent butyl ester of 2,4-D, 20 per cent isobutyl ester of 2,4,5-T and 30 per cent n-butyl ester of 2,4,5-T. The details of this work have not been published but have appeared in summary form in a review. *(8)* (Table 4)

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TABLE 3.—SUMMARY OF ORAL TOXICITIES OF A VARIETY OF PHENOXY ACETATE HERBICIDAL FORMULATIONS. ROWE AND HYMAS (17)

Material	Species	Sex	Vehicle	$Ld.^{50}$ (19/20 confidence limits) (mg./kg.)
2,4-Dow weed killer	Guinea pigs	F	Water	Range 2,000 (1,000–3,000)
2,4-Dow weed killer (formula 40)	Rats	F	Water	Range 850 (700–1,000)
Esteron 44	Rats	M	Olive oil	Range 650 (300–1,000)
Esteron 245 (old)	Rats	F	Emulsion in water	Range 1,000 (300–2,000)
Esteron 245 (new)	Rats	M	Olive oil	Range 800 (600–1,000)
Esteron ten-ten	Rats	F	Olive oil	760 (660–860)
Brush killer 50–50	Rats	F	Emulsion in water	1,070 (700–1650)
	Guinea pigs	F	Emulsion in water	1,160 (820–1,630)
	Mice	F	Corn oil	800 (624–1,070)
	Rabbits	F	Undiluted	Range 1,420 (500-2,000)
	Chicks	M and F	Undiluted	4,000 (2,700–5,000)
Brush killer T	Rat	F	Emulsion in water	1,200 (783–1,850)
	Guinea pigs	F	Emulsion in water	1,410 (875–2,290)
	Mice	F	Olive oil	1,230 (938–1,620)
	Rabbits	M	Undiluted	849 (604–1,190)
	Chicks	M and F	Undiluted	2,000 (1,350–2,960)
Brush killer 76	Rats	F	Corn oil	Range 750 (500–1,000)
Brush killer 76E	Rats	F	Corn oil	Range 300 (250–1,000)
Esteron brush killer (old)	Rats	M	Emulsion in water	Range 1,000 (300–3,000)
Esteron brush killer (new)	Rats	M and F	Corn oil	860 (800–930)
	Guinea pigs	M	Corn oil	1,220 (1,040–1,430)
	Guinea pigs	F	Corn oil	1,600 (1,390–1,840)
	Rabbits	M and F	Corn oil	960 (790–1,160)
	Chicks	M and F	Corn oil	Range 2,000 (1,000–3,000)
	Steers		Undiluted	Greater than 1,000

TABLE 4.—ACUTE ANIMAL TOXICITY OF PURPLE (8)

Route	Toxicity	Dosages (mg/kg)		
		Rat	Rabbit	Dog
Oral	LD^{50}	566	-	-
	LD^{5}	213	-	-
Intraperitoneal	LD^{50}	586	1,994	a 500
	LD^{5}	121	363	>250
Intratracheal	LD^{50}	560	-	a 500
	LD^{5}	244	-	>250
Percutaneous	LD^{50}	5,562	12,034	-
	LD^{5}	3,178	493	>1,250

a—approximation

There have been a few accounts of testing for acute toxicity of 2,4,5-T on domestic animals *(14, 17)*. These indicated that repeated doses of 100 mg/kg of 2,4,5-T were tolerated without over signs of illness in sheep and steers. In one instance 1000 mg/kg/day proved fatal to a steer after the third day. 500 mg/kg/day provoked signs of acute toxicity in steers after the third day *(17)*. The numbers of animals used in these studies were very small (single animals in some cases).

It has been assumed by some that the metabolism (and, hence, toxicity) of 2,4,5-T would resemble that of the other phenoxy acid herbicides. This is probably a reasonable assumption although it has not been systematically examined. There have been two recent reviews of the toxicity of phenoxy acid herbicides *(3)*, *(19)*. Included in these reviews are accounts of acute human toxicity of 2,4-D. The accounts include incidents of excessive occupational exposure, suicidal efforts, intended oral feeding and parenteral administration as a form of treatment for coccidioidomycosis. From descriptions such as these, it has been inferred that around 50 to 100 mg/kg of 2,4-D is acutely toxic to humans. However, there are inconsistencies in this scanty information.

OCCUPATIONAL EXPERIENCE

Occupational exposures (in the 2,4,5-T manufacturing process have provoked illness in workers. However, these effects have been attributed to the dioxin impurity (tetrachlorodibenz-p-dioxin). (See Section III, Chemistry). The toxicity of this impurity is considered later in this section.

NATIONAL CANCER INSTITUTE SCREENING STUDY FOR CARCINOGENESIS AND TERATOGENESIS

In 1964, the National Cancer Institute contracted for a screening study of a number of pesticides. Among the purposes of this large scale examination was to determine whether compounds in common use might be tumorigenic, or teratogenic or mutagenic *(12)*. The results of

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testing for carcinogenesis have been summarized by Innes et al. *(9)*. The results of testing for teratogenesis with 2,4,5-T have been analyzed and summarized by Courtney et al. *(2)*.

Screening for tumorigenicity was performed on two hybrid strains of mice. The materials, which were from commercial lots, were given by single subcutaneous injection or by continuous oral feeding. For each dose and each strain, 18 animals of each sex were used. Oral feeding was started when the animals were seven days old and was continued for 18 months. The dose chosen corresponded to a maximal tolerated dose. This was the experimentally determined maximum level resulting in zero mortality for 19 daily doses. The dose of 2,4,5-T used in the oral feeding studies was 21.5 mg/kg. Of the 72 mice which started the study, 12 died or were cannibalized before the end of the 18 months. Of those surviving, nine animals exhibited tumors. Of the total number necropsied (survivors plus premature deaths), 12 animals exhibited tumors. These included 4 reticulum cell sarcomas, 2 pulmonary adenomas, 5 heptomas, and 1 benign calcifying epithelioma.

These results were compared with the tumor incidence in a group of untreated control animals and in a group of animals treated with known tumorigens. 2,4,5-T was not found to provoke a significant increase in tumors after chronic administration.

In addition to 2,4,5-T, several related phenoxy compounds were also screened for tumor production. The compounds included:

2,4-D
2,4-D isopropyl ester
2,4-D butyl ester
2,4-D isooctyl ester
α-(2,4-dichlorophenoxy) propionic acid
α-(2,5-dichlorophenoxy) propionic acid
α-(2,4,5-trichlorophenoxy) propionic acid

Three of these compounds administered by the subcutaneous route [α-(2,4-dichlorophenoxy) propionic acid; α-2,4,5-trichlorophenoxy) propionic acid; and 2,4-D isopropyl ester] elicited an increase in tumor incidence in comparison with negative controls but the statistical significance was less than 0.02.

Screening for teratogenic effects was performed on four strains of mice and, in the case of 2,4,5-T, on one strain of rats. 2,4,5-T was one of 53 compounds examined in this study. Other related agents included were:

2,4-D
2,4-D isopropyl ester
2,4-D butyl ester
2,4-D isoctyl ester
2,4-D methyl ester
2,4-D ethyl ester
α-(2,5-dichlorophenoxy) propionic acid

[p. 43]

2,4-dichlorophenol
2,4,5-trichlorophenol
2,4,6-trichlorophenol

Compounds were administered subcutaneously in solution of dimethyl sulfoxide in maximally tolerated doses to pregnant female animals. Administration occurred between the 6th and the 14th days of gestation in mice. The animals were sacrificed on the 18th day and the fetuses were examined for abnormalities. With the finding of apparent increase in birth defects, the experiments were repeated with oral administration of the agents. Because of the findings of an increase in birth defects in the case of 2,4,5-T, this compound was studied more intensively (wider range of doses and two species of animals).

Evaluation compared the influence of these chemicals on the total incidence of birth defects. In addition, a further analysis attempted to reduce the interlitter statistical influences by calculating the incidence of birth defects on a litter-by-litter basis *(2)*.

2,4,5-T was tested in the C57BL/6 and AKR strains of mice, and in a hybrid strain produced by mating C57BL/6 females with AKR males. Three dosage levels (21.5, 46.4, and 113.0 mg/kg) were used orally and by injection. Numbers of litters varied from 6 to 18 in the experimental animals (6 to 12 in the orally fed animals). Three different patterns of dosage and sacrifice were used (dosage during days 6–14, 6–15, and 9–17). The findings from this set of experiments were increases in incidence of fetuses with cleft palate and fetuses with cystic kidney when compared to controls. There was also an indication of a dose-response relationship. Table 5, reproduced from Courtney *et al. (2)*, summarizes the findings. The numbers in the columns representing the percentages of abnormal fetuses per litter were derived by averaging the percentages of abnormalities per litter for each dosage.

Because of these results, an additional series of experiments was conducted in Sprague-Dawley rats. Four dosage levels were used (4.6, 10.0, and 21.5 and 46.4 mg/kg). Two types of fetal abnormalities were recognized, cystic kidney and enlarged renal pelvis. Courtney et al. *(2)*, in reviewing these experiments, analyzed the results on the basis of abnormalities per litter. In reducing the sample size from the total number of fetuses to the total number of litters, these authors felt that the resulting sample size for the 21.5 mg/kg dosage was too small and, hence, deleted the data for this dose. Table 6 is a summary of these data.

The inferences which have been drawn from these experiments are that 2,4,5-T appears to provoke a higher than expected level of fetal death and fetal abnormality in rats and mice in the dosages used. Further, there appeared to be a suggestion of a dose-response relationship over the range of doses used. [p. 44]

Comments of the screening study contracted for by the National Cancer Institute have already been published *(18)*. The following observations by the Panel are concerned with the portion of this study in which the teratogenic potential of 2,4,5-T was tested.

1. The study involved a great number of variations in procedure (strain of mice used, dates when tests were performed, and routes of administration). These variations make the task of evaluation difficult.

2. Too few animals and litters of animals were used. Since biological variability is considerable, the sample size must be adequately large to demonstrate specific effects of the chemical agents in question. At least 10 pregnant females to assure at least 100 conceptions is suggested. The Food and Drug Administration suggests 20 females per test group.

3. There appears to be an unusually high level of embryo lethality and teratogenicity among untreated and vehicle-treated groups. Either the experimental conditions were less than optimal or the strain of animals was developmentally unstable.

4. The strain of mouse most often used (C57BL/6) appeared to have had undesirable traits as a test animal, being variably and uncertainly responsive to the substance being tested. A reasonably homogeneous, colony-bred stock which has been maintained in the laboratory long enough for the investigator to have accumulated substantial background data on fecundity, spontaneous malformation and intrauterine death rates is generally regarded as preferable to inbred stocks for teratological testing.

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TABLE 5.—TERATOGENIC EVALUATION OF 2,4,5-T IN MICE (2)

Compound	Vehicle	Dose (mg/kg)	Litters (No.)	Live fetuses per litter (av. No.)	Fetal mortality per litter (percent)	Abnormal litters (percent)	Abnormal fetuses per litter (percent)	Percentage of fetuses per litter with:	
								Cleft palate	Cystic kidney
C57BL/6 strain treated days 6 to 14									
Nontreated	None	None	72	5.8	26	38	11	<1	1
Control	DMSO	(*)	106	5.5	29	42	12	<1	2
Control	Honey	(*)	32	7.1	15	41	14	0	1
2,4,5-T	DMSO	21.5	6	7.7	3	50	12	0	0
2,4,5-T	DMSO	113.0	18	4.4	42	†86	†57	†22	†41
2,4,5-T	Honey	46.4	6	8.5	8	‡100	‡37	2	†33
2,4,5-T	Honey	113.0	12	4.8	†47	†100	†70	†23	†48
C57BL/6 strain treated days 9 to 17									
Nontreated	None	None	8	5.1	36	71	31	0	7
Control	DMSO	(*)	10	6.1	23	30	8	0	0
2,4,5-T	DMSO	113.0	10	7.7	11	†100	†77	†29	†60
AKR strain treated days 6 to 15									
Nontreated	None	None	58	7.1	16	19	5	<1	<1
Control	DMSO	(*)	72	6.9	15	24	4	<1	<1
Control	Honey	(*)	12	8.8	9	0	0	0	0
2,4,5-T	DMSO	113.0	14	6.9	23	†71	†29	†28	1
2,4,5-T	Honey	113.0	7	5.3	‡42	†100	†55	†55	0

*Dose, 100 μl per mouse.

†P=.01.

‡P=.05.

TABLE 6.—TERATOGENIC EVALUATION OF 2,4,5-T IN RATS

Compound	Vehicle	Dose (mg/kg)	No. of litters	Average No. live fetuses/litter	Percent fetal mortality/litter	Percent abnormal litters	Percent abnormal fetuses/litter	Percent of fetuses per litter with:	
								Enlarged renal pelvis	Cystic kidney
Nontreated	None		7	9.9	11	43	9	9	0
Control	Honey	(†)	14	8.7	1	57	12	12	<1
2,4,5-T	Honey	4.6	8	8.2	12	88	**36	11	21
2,4,5-T	Honey	10.0	7	7.1	***28	86	**46	17	**30
2,4,5-T	Honey	46.4	6	2.7	***59	67	§60	27	§33

†200 µl/rat (2).
**Statistical Significance Level=0.05.
***Statistical Significance Level=0.01.
§The sample size was possibly too small to show a significant difference.

5. It is puzzling that virtually no skeletal malformations were encountered in either controls or test group. Skeletal defects usually account for a substantial part of the easily detectable malformations that occur spontaneously or after treatment in rodent species. Hardly a strain that has been carefully studied in properly cleared and stained specimens has failed to show vertebral and rib variations.

6. There were some known teratogens used in these experiments (trypan blue, 6-aminonicotinamide). It is puzzling to find that these agents failed to produce significant teratogenic and embryolethal effects consistently. This raises questions about the precision with which these teratogenicity tests were performed.

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7. 2,4,5-T appeared to be clearly teratogenic in two strains of mice treated with 2,4,5-T at 113 mg/kg via either of the two routes of administration. In rats, 2,4,5-T appeared only equivocally teratogenic at any dosage but clearly embryo-lethal from 10.0–46.4 mg/kg.

8. The lack of an unequivocally defined dose-response relationship renders these results less than completely satisfying.

REPORTS OF BIRTH DEFECTS AMONG HUMANS FOLLOWING EXPOSURE TO 2,4,5-T

Shortly after the report of the teratogenesis screening in experimental animals of pesticides, there appeared a series of articles in the lay press which described the occurrence of birth defects in parts of Vietnam where defoliants had been used. These articles appeared in at least six different newspapers in South Vietnam between June 26 and July 5, 1969. Both congenital abnormalities and hydatid moles* were described. Translations of the articles have alluded to the possibility that defoliants might be responsible for these defects. The implication was offered that these abnormalities had increased in frequency in the recent past. No documentation has been available.

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* (An abnormality of pregnancy which involves the placenta and the membranes surrounding the fetus.)

TOXICITY OF DIOXIN

It was pointed out in an earlier section of this report that one of the impurities which arises in the manufacturing process of 2,4,5-T is 2,3,7,8-tetrachlorodibenzo-p-dioxin. This substance has considerable interest because it is highly toxic, because a close relative was a toxic constituent in chicken feed and because it has caused chloracne, a severe skin disease, among workers engaged in the manufacture of 2,4,5-T.

The dioxin impurity has assumed a further importance as an impurity in commercially available 2,4,5-T. With the observation that production lots of 2,4,5-T containing approximately 27 ppm dioxin could be teratogenic, it became important to ascertain whether it was 2,4,5-T itself or some impurity which was the teratogen. Recent experiments at the National Institute of Environmental Health Services indicate that partially purified 2,4,5-T (<0.1 ppm tetrachlorodibenzo-p-dioxin) shows teratogenic activity in the mouse. Pure tetrachlorodibenzo-p-dioxin shows teratogenic activity also, but not at low enough doses to account for the activity of the partially purified 2,4,5-T. We cannot exclude the possibility that other impurities may contribute significantly to the observed teratogenic activity of 2,4,5-T.

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In the following paragraphs, the history of the discovery of dioxin is examined in relation to the experimental observation of the teratogenic properties of 2,4,5-T. Secondly, data on the toxicity of this material are presented.

In March 1949, an accident occurred at a 2,4,5-T plant owned by the Monsanto Chemical Company which led to the release of some of the intermediate chemicals into the plant. As a result, 117 cases of a severe skin disease known as chloracne were found among the exposed workers. Chloracne is characterized by comedones, blackheads, inclusion cysts, and pustules with eventual scarring over the neck, back, and chest. In addition to the cases which were traced to the accident, a number of other clinical cases of chloracne were recognized among workers in the 2,4,5-T plant who were not in the vicinity of the accident. *(10)* Kimmig and Schulz *(11)* reported in 1957 that chloracne occurred among workers engaged in the manufacture of 2,4,5-T in Germany. These authors demonstrated that the agent responsible for chloracne was tetrachlorodioxin. In 1964, the demand for 2,4,5-T in the United States began to rise mainly due to its increasing use as a defoliant in Vietnam. A greater demand was placed on each of the domestic manufacturers to produce more herbicide. Coincident with the increased production was the discovery of chloracne among some 60 2,4,5-T workers. *(7)* The Dow Chemical Company reduced its operations substantially for a period of several months in order to investigate the origin of the toxic hazard. It was found that the amount of dioxin formed varied with the temperature and pressure of the early reaction steps. The Dow Chemical Company made its findings known to the other domestic manufacturers. Looking back it is evident that dioxin levels varied widely among commercial 2,4,5-T samples, as seen in Table 4 of Section III. Rigorous control is now exercised to reduce dioxin levels in the final product to less than 1 ppm.

A recent review of occupational disease attributed to dioxin has been prepared by Poland *et al. (15)*. These authors studied 73 male employees in a 2,4,5-T factory, some of whom had been observed six years previously by Bleiberg *(1)* who then noted the prevalence of chloracne. Poland et al. *(15)* also found chloracne among the same population although estimates of exposures were not made. Poland attributed the chloracne to the dioxin impurity. They also examined the prevalence of a type of porphyria, thought to be toxic in origin, known as porphyria cutanea tarda (elevated urinary porphyrin excretion, skin fragility and vesicular eruptions). Uroporphyrinuria had been noted during the early visit to the plant by Bleiberg *(1)* but it was not found during the later study. Elevated urinary coproporphyrin levels were noted, however, but there appeared to be no correlation with the severity or presence of chloracne *(1, 15)*. The later series of observations found much of the chloracne still remaining

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but the porphyria had disappeared. Chloracne was attributed to the dioxin impurity but the origin of the porphyria was less certain.

In order to measure the toxicity of the dioxin impurity, the Dow Chemical Company undertook a series of acute toxicity studies on small animals in 1967 *(16)*. Single doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin were administered orally to lots of five animals for each of several doses. The number surviving and the time of death were noted. The animals used were male rats, female rats and female guinea pigs. Table 7 gives the results of these experiments:

TABLE 7.—*Single-dose oral toxicity of dioxin (18)*

Species	LD_{50} mg/kg
Male rat	0.022
Female rat	.045
Female guinea pig	.0006

With this background in mind, the purity of the 2,4,5-T material used in the National Cancer Institute screening study assumed a new importance. A sample of this material was submitted to chemical analysis by gas chromatography. The result was the finding of 27 ± 8 ppm of dioxin.

TESTING FOR TERATOGENICITY

The study of teratogenic effects in experimental animals is characterized by a great deal of empiricism. However, in general testing for teratogenic potential is a more manageable problem than are a number of other types of biologic testing. There are large numbers of agents known to be teratogenic to animals. In fact, it has been held that virtually any material is potentially teratogenic if administered in an appropriate dose at the critical time in gestation. Interestingly, however, only a few chemicals have been recognized as human teratogens.

In general, an embryo-toxic dose of a material is separated from a maternal toxic dose by a small margin (perhaps no more than a factor of 10). Only slightly below the embryo-lethal or toxic dose is a no-effect dose (separated, perhaps, by a factor of 2). Between the highest level which has no effect on the developing fetus and the embryo toxic level is a steep dose-response relationship. In testing for teratogenicity, the lowest dose on the dose-response curve (threshold for any embryo toxicity) is identified. All doses below this level are, by definition, no effect doses. By accepting an extra margin of safety below this dose (a factor of 1/10–1/100), reasonable freedom from teratogenic effects can be predicted.

A problem arises in extrapolating findings in experimental animals to man. The embryotoxicity of a chemical agent is, in theory, a function

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of the degree of exposure of the developing embryo to the agent. This appears to be a function, in turn, of the persistence of the material in the maternal circulation. Thus, in order to extrapolate animal findings to humans, the animal must be "calibrated" to humans for each chemical agent. That is, the rate of disappearance of the agent from the animal circulation must be compared quantitatively to that in humans. As a first approximation, corresponding doses in mg/kg would be taken as proportional to the blood clearance rates for the two species.

These principles make possible the design of testing procedures for reproductive defects caused by chemical substances. The scheme described is of a general nature but can be applied to 2,4,5-T. The first step involves determination of the chemical nature of the material in question. Secondly, animal studies should be done to establish embryotoxic levels. In the case of 2,4,5-T, some additional studies have been carried out to confirm the results of the National Cancer Institute screening study. In addition, studies should be undertaken on pure 2,4,5-T and on its various impurities to identify the teratogenic agent or agents. Hybrid strains of animals should be used rather than highly inbred strains. At least two animal species should be used. Preferably strains of colony or random bred rats and mice should be used which have been maintained in the laboratory long enough for the investigator to have accumulated substantial background data on fecundity, spontaneous malformations and intrauterine death rates.

By careful testing, using a small series of doses, a TD_{50} dose (that dose which will cause teratogenesis in 50 percent of fetuses) can be ascertained. At the low end of the dose-response curve is found, presumably, a threshold dose below which no detectable teratogenic effects would be expected. Actual experimentation locates TD_{small} at which teratogenicity occurs in only a few percent of all fetuses.

The next step is to compare the expected human exposure with the animal TD_{small}. If these differ by as much as a factor of 100, it would seem reasonable to consider the material safe with regard to teratogenesis. If the difference between the human exposure and the animal TD_{small} is as little as a factor of 10, the margin probably is insufficient. Between 100 and 10 lies a certain amount of flexibility for further action. Finally, in order to extrapolate the animal data to human experience, rates of excretion and detoxification in animals and humans should be compared.

SUMMARY OF RECENT EXPERIMENTS

Following analysis of the results of the screening study carried out for the National Cancer Institute, it was felt that confirmatory studies should be undertaken. Two sets of experiments were begun independently by the Dow Chemical Company and by the National

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Institute of Environmental Health Sciences. At the time of this writing, some of these experiments have been completed and the results have been reportd.

1. Dow experiments.

2,4,5-T (containing ⋚ 1.0 ppm dioxin) was administered orally to pregnant Sprague-Dawley rats on days 6–15 of gestation. *(6)* The doses used were 1, 3, 6, 12, and 24 mg/kg/day. The 2,4,5-T was administered in 0.25% Methocel®. The results were compared with those obtained from controls which received the vehicle only.

No clinical or gross pathologic signs of adverse effect were observed in treated females during the period of treatment. Litter size, number of fetal resorptions and birth weights appeared to be unaffected. Furthermore, there was no increase in the incidence of birth defects compared to control animals.

In a related study by the Dow Chemical Company on the teratogenicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin *(4)*, this material, in pure form, was administered to pregnant Sprague-Dawley rats. The doses used ranged from 0.03 to 8.0 mg/kg/day. Between 0.125 and 0.5 mg/kg, intestinal hemorrhages were seen in the fetuses. Dioxin was very embryolethal at the highest dosages (2.0 and 8.0 mg/kg).

2. NIEHS experiments.

The National Institute of Environmental Health Sciences undertook a series of experiments in which 2,4,5-T (containing various amounts of dioxin impurity) was administered to pregnant mice and rats *(13)*. Three strains of mice were used (1 random bred and 2 inbred strains) and a random bred strain of rats. Four different lots of 2,4,5-T were employed:

a. "Eastman Organic"—contained ⋚ 1.0 ppm dioxin.
b. "Dow Technical"—contained ⋚ 0.5 ppm dioxin.
c. "Dow Pure"—contained ⋚ 0.1 ppm dioxin.
d. 2,4,5-T samples used in the original tests performed for the National Cancer Institute—containing about 27 ppm dioxin.

In addition, pure 2,3,7,8,-tetrachlorodibenzo-p-dioxin was administered to a series of mice and rats.

These materials were tested in various dosages in mice by injection in dimethyl sulfoxide (DMSO). In the random bred (Charles River) mice, the dosage schedule for 2,4,5-T covered the range of 50–150 mg/kg/day. In the other strains of mice, a narrower range of doses was tested. In rats, the dosage range was 10.0–21.5 mg/kg/day and here the material was administered orally in sucrose. Pure dioxin was administered subcutaneously in DMSO in rats and mice (1 and 3 mg/kg/day in mice and 0.5 and 2 mg/kg in rats).

In mice, both 2,4,5-T (in the purest form available) and dioxin produced birth defects and increased fetal toxicity. The birth defects were qualitatively similar to those seen previously in the National Cancer Institute screening study and included cleft palates and

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renal defects. In rats renal defects and excess fetal mortality were seen but seemed to be related to dioxin content rather than 2,4,5-T.

3. FDA Experiments (unpublished data acquired in the spring of 1970).

Teratogenic studies were performed by giving the test compound by oral intubation to pregnant hamsters on day 6 through 10 of organogenesis. Embryos were removed by caesarian section on day 14 of pregnancy. Samples of 2,4,5–T tested were:

a. "Dow Technical"—contained ⋜ 0.5 ppm dioxin.
b. "Dow Technical"—contained ⋜ 0.1 ppm dioxin.
c. "Dow Pure"—contained ⋜ 0.1 ppm dioxin.
d. Hercules X-17394—contained no detectable dioxin.
e. Monsanto NL-07-020—contained 2.9 ppm dioxin.
f. "K & K" sample—contained about 45 ppm dioxin.
g. Eastman Kodak (recrystallized in FDA)—contained no detectable dioxin.

In addition pure 2,3,7,8-tetrachlorodibenzo-p-dioxin (Dow) was administered to hamsters.

These materials were tested in various doses from 40–100 mg/kg. All of the 2,4,5-T samples produced increased embryotoxicity and gastric and/or intestinal hemorrhages. Birth defects consisted chiefly of poor head fusion and absence of eyelids.

The pure tetradioxin produced increased fetal toxicity at 0.31 and 1.43 μg/kg and gastric and/or intestinal hemorrhages at the lowest dose, 0.02 μg/kg.

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RESIDUES OF 2,4,5-T IN THE ENVIRONMENT

Summary

2,4,5-T residues disappear from soil with moderate speed, probably through action of microorganisms, persisting as long as three months. During this period they are potentially available for transport to non-target areas.

It appears unlikely that residues from recommended applications of 2,4,5-T could appear in hazardous quantities in water.

Typical applications are to forested areas or those infested by weeds where most of the herbicide appears to be intercepted by the plants. Residues do not seem to persist in water, however, they do remain longer in bottom sediments.

Residues from rangeland and pasture applications may find their way into cattle permitted to graze soon after spraying. Cattle excrete the intact herbicide rapidly but 2,4,5-T residues have occasionally been found in meat and dairy products. Although the residue levels are low, they dictate caution about pasturing soon after rangeland treatment.

The rate of application of 2,4,5-T in Vietnam is 13 lbs. of the butyl ester per acre (26 lbs. of Orange per acre). This rate is about 2–6 times as high as that used on rangelands domestically. Moreover, much larger areas are treated in Vietnam. Orange is not used on food crops but on forests. Hence, human exposure to contaminated food crops would be unlikely. If, during the vulnerable period of gestation, all a pregnant mother's food came from locations treated with Orange at 26 lbs/acre within the preceding week or so, the daily dose of 2,4,5-T might conceivably reach 15 mg/kg/day, which by comparison to some animal data might prove to be embryotoxic. Such estimates are based on a very extreme, worst-case calculation.

RESIDUES OF 2,4,5-T RESULTING FROM RECOMMENDED USES IN THE UNITED STATES

The herbicide 2,4,5-T is applied for weed control to a relatively few crops. However, it is used more extensively for control of weeds in rangelands and pastures, non-croplands and aquatic areas (Table 1).

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It is not considered to be a persistent pesticide by comparison with many of the chlorinated hydrocarbon insecticides. Nevertheless, its use at rates of recommended application results in measurable levels of residue in soils, water, air, plants, and animals which persist for relatively short periods of time after application. The potential effects of such residues on the health of man and other animals have been little studied and are poorly understood. Data available suggest that residues resulting from recommended rates of application are not of sufficient magnitude to justify concern as potential health hazards. Unfortunately, most of the toxicity studies conducted thus far have been relatively short-termed and of value for determining acutely toxic doses only. Substantial amounts of data are available of the sort reported by

Palmer and Radeleff *(14)*. Data from such studies indicate that 2,4,5-T is not acutely hazardous for cattle, sheep, and chickens when applied at recommended rates. They considered rates of application above 30 pounds per acre to be hazardous.

Recent concern over the possible adverse effects of long-term exposure to relatively small amounts of 2,4,5-T as residues in food, feed, and water makes it desirable to review the information available on levels and persistence of such residues.

1. **Soils**—The possibility of residual toxicity to crops grown on soils treated with 2,4,5-T has emphasized the need for information on the levels of residues resulting from various rates of application and their persistence. Substantial amounts of data have been accumulated on these points and there is relatively good agreement in results of most studies. Taking into account differences in soil type, temperature, and moisture and the phenomenon of bacterial proliferation in response to a new substrate, it appears that 2,4,5-T residues in soils may persist for as long as three months. The persistency of residues seems to be independent of the rate of application.

TABLE 1.—SOME EXAMPLES OF DOMESTIC USES OF 2,4,5-T FOR CONTROL OF WEEDS. (SUGGESTED GUIDE FOR WEED CONTROL, 1969). U.S.D.A. AGRICULTURE HANDBOOK NO. 332

Crop or area	Rate of application pounds per A
Sugarcane	1.0
Grasses grown for seed	0.75
Rice	0.5–1.5
Permanent pastures and rangelands	0.5–8.0
Non-cropland, rights-of-way, floodways, ditchbanks, fance rows, and industrial sites	1.0–4.0
Aquatic weeds	1.0–4.0

Laboratory studies suggest that breakdown of 2,4,5-T residues in soils result from the action of microorganisms which are capable of using these chemicals as sources of energy and carbon. Two species have been reported to use 2,4,5-T as a source for energy and carbon. *(1)* The microbiological degradation of the phenoxyacetic acid herbicides in the forest floor material probably resembles that in soils. *(13)*

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Under the conditions of this environment substantial amounts of 2,4,5-T remained after 4 months. The relatively rapid degradation of residues of phenoxyacetic acid herbicides in the soil makes it unlikely that there will be any accumulation of 2,4,5-T from one season to the next. Rates of removal from soils by plants and invertebrates are uncertain.

A major concern about residues of persistent pesticides is that they do not always stay in the target area. The fact that residues of 2,4,5-T may remain in the soil for periods of three months, or more, makes it subject to transport to non-target areas. Soil particles contaminated with 2,4,5-T may be transported by wind or water to areas far removed from the site of application. The extent to which this occurs seems to have received little or no attention.

The choice among esters is often influenced by such considerations as reduced volatility (which may reduce spreading to non-target plants), slowness of hydrolysis, and avoidance of crystallization after the vehicle has evaporated.

Experiments on leaching of 2,4,5-T products and vehicles suggest that amine salts are leached more rapidly than the free acid *(8)*.

2. **Water**—Residues of pesticides in water are of concern because of the possibility of their getting into drinking water for man and other animals, of their potential adverse effects on aquatic organisms, and of the potential adverse effect on sensitive crop plants of irrigation water contaminated with these chemicals. Contamination of surface waters with herbicide residues is a matter of special concern since surface water provides most municipal water supplies. Nearly all of the water for livestock and other animals is supplied from surface water.

Since nearly 100 million acres of land are treated with herbicides in the United States each year, about 3 million acres of which are forest or rangelands, it is inevitable that substantial contamination of surface water occurs. However, most of the contamination is indirect as a result of drift from target areas.

The manner in which contamination occurs, whether from drift or from direct application, determines the level of residues deposited. In applications made to forested areas or to bodies of water heavily infested by weeds extending above the water, much of the total amount of herbicide applied will not reach the water directly. As much as 88 percent of the total amount applied may be intercepted by such plant covers as liveoak which are much less dense than those of water hyacinth or alligator weed. *(16)* There appears to be little information available on the possibility of future release to water of residues in plants.

Streams in forests in Oregon sprayed with 2,4,5-T or mixtures of 2,4,5-T and 2,4-D in a 1:1 ratio at the rate of 2 pounds per acre showed maximum residues of 70 ppb which disappeared within 17 days. *(15)*

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Even at the heaviest rate of application recommended for control of weeds in permanent pastures and rangelands and aquatic species, 2,4,5-T residues would not be substantial even at the maximum levels that could be expected. For example, 8 pounds of herbicide per acre applied to a body of water 3 inches deep would result in residues of only 12 ppm, Table 2. An animal drinking from even such an unusually shallow source could not get a dose that would be expected to cause chronic toxicity. For example, a cow weighing 500 kg may be expected to drink as much as 50 l. of water per day during the warm seasons of the year which would result in the ingestion of about 1.2 mg/kg/day. However, a more realistic example could be expected from applications of 2,4,5-T to rangelands at 4 pounds per acre. Treatment of a body of water one foot deep at this rate would result in residues of only 1.5 mg/l. A 500 kg cow drinking from such a source could get no more than 0.15 mg/kg/day.

Adverse effects of residues of 2,4,5-T on aquatic species such as fish and some of the bottom dwelling invertebrates might be expected from the heavier recommended uses of this herbicide to shallow bodies of water. For example, 24-hr. LC_{50}* for bluegill is 1.(4 ppm for the butoxyethanol ester of 2,4,5-T (see table 1 on page 67). Concentrations higher than this would result from the direct application of 4 pounds per acre to bodies of water no more than 6 in. deep.

TABLE 2.—ESTIMATED MAXIMUM LEVEL (MG/L.) OF RESIDUES OF 2,4,5-T AT VARIOUS RATES OF APPLICATION TO BODIES OF WATER RANGING FROM 3 INCHES TO 10 FEET IN DEPTH.

Depth of Water	Rates of application, pounds per A							
	1	2	4	6	20	26	80	100
3 inches	1.5	3.0	6.0	9.0	30.0	39.0	120.0	150.0
6 inches	0.75	1.50	3.0	4.50	15.00	19.50	60.0	75.0
1 foot	0.38	0.75	1.50	2.25	7.50	9.75	30.0	37.50
2 feet	0.19	0.38	0.75	1.13	3.75	4.88	15.0	18.75
3 feet	0.13	0.25	0.50	0.75	2.50	3.25	10.0	12.50
4 feet	0.09	0.19	0.38	0.56	1.88	2.44	7.50	9.38
5 feet	0.08	0.15	0.30	0.45	1.50	1.95	6.00	7.50
6 feet	0.06	0.13	0.25	0.38	1.25	1.63	5.00	6.25
7 feet	0.05	0.11	0.21	0.32	1.07	1.39	4.29	5.36
8 feet	0.05	0.09	0.19	0.28	0.94	1.22	3.75	4.69
9 feet	0.04	0.08	0.17	0.25	0.83	1.08	3.33	4.17
10 feet	0.04	0.08	0.15	0.23	0.75	0.98	3.00	3.75

There appears to be little likelihood of 2,4,5-T appearing in hazardous quantities in ground water or drainage channels from local applications. Brown and Nishoka *(3)* reported that 2,4,5-T was not detectable in samples of water-suspended sediment mixtures from 11 streams in the western United States.

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* LC_{50}, median lethal concentration of a toxicant, typically placed in the ambient environment of the organisms whose survival is measured. Usually, the environment in question is aquatic. The terms, LD_{50} and LC_{50}, may be used interchangeably for aquatic organisms.

However, a subsequent study of the same streams *(11)* making use of improved techniques showed 28 of 235 samples taken from 17 rivers during 1966–68 to be positive for 2,4,5-T residues. Twenty-one of these [p. 57] were from three rivers, the Arkansas, Brazos, and Canadian. All of the seven samples taken from the latter were positive. The amount of residues found was extremely small, ranging from 0.01 to 0.07 ppb. Samples were taken uniformly throughout the year and there appeared to be little effect of season on incidence or levels of 2,4,5-T residues.

Samples were analyzed as received with no effort made to separate water and sediments. It is possible that a high percentage of the residues was contained in the sediment since there is evidence that phenoxyacetic acid herbicide residues persist longer in sediments than in water. In either case, these data provide strong evidence that residues of 2,4,5-T in water which result from use of the herbicide in this country are not hazardous.

3. **Plants**—The levels of residues of 2,4,5-T in plants have received much less attention than has been devoted to insecticide residues. The comparatively short residual life of this material together with the fact that it is usually applied several weeks, or even months, in advance of harvesting dates, has allowed it to be used in most cases without danger of significant residues in the harvested product. However, it is recommended for control of weeds in permanent pastures and rangelands at rates which result in significant levels of residues that have been reported to persist, under some conditions, for as long as 6 weeks, Table 3. However, there has been relatively good agreement in results obtained by various workers who have reported on persistence of residues of 2,4,5-T applied to forage grasses in rangelands and pastures. The data of Morton, *et al. (12)* indicate levels in pasture grasses ranging from 10 to 32 ppm after about one month which agrees reasonably well with the 7 ppm reported by Baur, *et al. (2)* in range forage grasses. [p. 58]

Substantial levels of residues occur in forage plants treated with 2,4,5-T at 2 lbs/acre, and appreciable quantities sometimes persist for as long as 3 weeks. This suggests that beef cattle permitted to graze pastures or rangelands immediately after treatment, or that dairy cattle permitted to graze such areas 7 days after application at maximum rates recommended, may be exposed to dosages that are too high for safety (Table 4). Estimates of the levels of residues that might occur in forage grasses treated

TABLE 3.—RATE OF DISAPPEARANCE OF 2,4,5-T RESIDUES FROM VARIOUS TYPES OF FORAGE CROPS, ESTIMATED FROM SEMI-LOGARITHMIC PLOTS IN FIGURES 1-4. (12)

No. days from treatment	Concentration, ppm (2,4,5-T)		
	2 pounds per A butoxyethylester	2 pounds per A acid	1 pound per A amine
0	300	100	100
2			
4			
7	130	70	70
14	70	35	45
21	55	20	30
28	45	15	15
35	32	12	10
42	20	11	8
49	12	11	6
56	7	11	5
63		8	4
70		7	3
77		6	3
84		5	2
91		4	2
98		3	2

at higher rates indicate a possibility of transfer of residues to milk and even chronic toxicity (Table 4). However, the fact that no evidence of toxic effects has been reported and that residues of 2,4,5-T have been rarely found, and even when found have been at very low levels in dairy products that have been analyzed by FDA in total diet studies, argues against the probability that residues of this herbicide in forage crops pose any significant hazard.

TABLE 4.—ESTIMATED RATES OF DISAPPEARANCE OF 2,4,5-T RESIDUES FROM FORAGE TREATED AT DIFFERENT RATES WITH CORRESPONDING MAXIMUM AMOUNTS OF HERBICIDE THAT MIGHT BE INGESTED BY CATTLE PASTURED ON FORAGE TREATED AT THE RATES INDICATED.

No. weeks after treatment	2,4,5-T butoxyethylester			
	2 lbs/A[2]		4 lbs/A[3]	
	mg/kg in forage	mg/kg/day[4] ingested	mg/kg in forage	mg/kg/day[4] ingested
0[1]	300	25	600	50
1	130	11	260	22
2	70	6	140	12
3	55	4	110	8
4	45	4	90	8
5	32	3	64	6
6	20	2	40	4
7	12	1	24	2
8	7	0.6	14	1.2

[1] Within 30 min. of treatment.

[2] Estimated from semilogarithmic plots of graph in Table 2. (16).

[3] Extrapolated from [2] using maximum rates of 2,4,5-T recommended for permanent pastures and rangelands in Agriculture Handbook No. 332, 1969.

[4] Assuming a 500 kg cow eating 45 kg forage per day.

4. **Animals**—Residues of 2,4,5-T in animals, as in plants have received much less attention than some of the fat soluble, long-persisting organochlorine insecticides. The residues that occur

from ingestion of the phenoxy herbicides are eliminated rapidly and there is evidence that accumulation occurs in only a few species. Erne *(6)* in one of the most thorough studies of the distribution and elimination of 2,4,5-T reported that it was readily absorbed and distributed completely in the body. He found that it was eliminated rapidly. Plasma half-life values from single oral doses of 100 mg/kg of the amine salt to male rats and pigs were 3 and 10 hours, respectively. Highest levels of residues were found in the kidney, liver, lungs, and spleen with levels sometimes exceeding plasma levels. There was little evidence of penetration into the brain or adipose tissues. The main

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excretory route was the kidney. His data *(7)* showing weak but "certain" protein binding of 2,4-D suggest that this may also occur with 2,4,5-T.

5. **Food and feed**—Results of studies of pesticide chemical residues in total diet samples by the Food and Drug Administration during the period 1964–68 provide convincing evidence that 2,4,5-T residues are not a significant health hazard in food in the United States. During this 5-year period 30 composite samples of about 82 food items each have been collected each year from retail markets in 25 or more cities. Each composite sample, representing a 2-week diet for a 16- to 19-year-old male, is analyzed by multiresidue methods for more than 60 chlorinated organic and organophosphorus insecticides and for herbicides, carbamates, and selected inorganic chemical residues. Examination of these samples is carried out at levels of sensitivity much lower than those normally used for products tested for compliance with tolerances.

Data reported for the period June 1967–April 1968 *(4)* show incidence and levels of 2,4,5-T residues that are typical. Only one sample of dairy products was contaminated. About 2 percent of dairy products and 1 percent of meat, fish, and poultry were reported to contain residues of 2,4,5-T. All of these residues were at trace levels, below 0.01 ppm. No residues of 2,4,5-T were found in any of the other 10 classes of foods.

It is significant that residues of 2,4,5-T were detected only in foods of animal origin. The most likely source is forage from pastures and rangelands treated with 2,4,5-T for weed or brush control.

Duggan and Lipscomb *(5)* summarized the results of sampling for herbicide residues in prepared food from the total diet studies over a period of four years. From these studies, they estimated the likely dietary intake of all of the herbicides searched for to below:

Year	Estimated dietary intake (mg/kg/day)
1965	0.0012
1966	0.00022
1967	0.00005
1968	0.0000E

Since 2,4,5-T residues are only a small percentage of these total herbicide residues found in foods it seems safe to conclude that there is little likelihood of exposure from this source.

Residues of 2,4-D and 2,4,5-T resulting from recommended uses by the military for defoliation.

All the available evidence indicates that 2,4-D and 2,4,5-T behave similarly in animals with respect to absorption, distribution, metab-

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olism, and elimination. Since mixtures of these herbicides are used in the defoliation program in Vietnam, it does not appear reasonable to consider them separately.

The large-scale application of 2,4-D–2,4,5-T mixtures for defoliating military target areas in Vietnam poses some possible unique hazards to humans. Application rates of about 26 lbs/acre of a 1:1 mixture of the n-butyl esters of the chemicals are generally heavier than those used for agriculture and brush clearing in the United States. (There have been a few, limited applications of 2,4-D reported to lakes, streams, and reservoirs in the United States at rates of 80–100 lbs/acre for aquatic weed control.) There are other differences. There are vastly greater areas involved in Vietnam. Because of the nature of the military targets—heavily wooded, jungle areas—it is not likely that many crops are grown in or near treated areas. Although defoliation procedures appear to be under rigid control with all reasonable precautions taken to prevent application to crops, the nature of military operations makes it likely that accidents may occur and that mistakes may be made which result in direct applications to non-target areas. In such cases it is possible that food crops and water supplies in restricted localities could receive heavy doses of the 2,4-D–2,4,5-T mixture. A much more likely possibility is drift of relatively small amounts of the herbicides to non-target areas. The n-butyl esters of both 2,4-D and 2,4,5-T are volatile and substantial amounts of both chemicals may vaporize at temperatures prevalent in Vietnam and escape from the target area.

If mixtures of 2,4-D and 2,4,5-T were applied directly to food crops at the rates being used in Vietnam for defoliation (about 26 lbs/acre), it is theoretically possible that amounts potentially hazardous to humans could be deposited on food. The butyl ester of 2,4,5-T applied to an improved pasture at the rate of 2 pounds per acre was found to result in an initial deposit of about 300 ppm on the forage *(12)*. Direct application to food crops at 26 pounds per acre could not reasonably be expected to result in initial residues greater than 3900 ppm. Assuming initial residues on food crops as high as 3900 ppm from direct application at the rate of 26 pounds per acre is unrealistic. Such an assumption requires that: 1) surface/volume ratios of food items be similar to that of forage grasses; 2) all portions of food items, e.g., husks of corn, peels of banana, shells of coconut, be consumed; 3) there is no loss of herbicide during preparation and cooking; and 4) translocation of herbicide into portions of the plants used for food, e.g., root crops, banana pulp, and coconut flesh and milk, results in residues as high as if these portions had been treated directly. None of these is true. Some items of food could not be contaminated by direct contact with the spray formulation. Translocation from foliage to underground roots of sweet potato and fruits of peanut

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and into aboveground fruits such as coconut would be required for these foods to be contaminated.

Table 5 breaks down an estimated diet for a 60-kilogram Vietnamese into three parts according to the rapidity with which 2,4-D and 2,4,5-T might be translocated into the portions consumed for food.

Table 6 estimates the maximum believable concentrations of the herbicides in such a diet as being 3900 ppm initially, 1560 ppm after one week and 910 ppm after 2 weeks (See Table 2 for estimated rates of disappearance of 2,4,5-T residues for forage). The maximum dosage retained, substantially greater than any realistic figures, is about 30/mg/kg/day.

The possibility that any of these assumptions might approach reality is probably nil. Many crops that are treated directly at such high rates show severe damage within a few days and would not be harvested. Translocation or penetration of residues into coconut meat and milk and banana pulp would take some time to occur, if at all, and would probably be at levels much lower than amounts

TABLE 5.—*Estimated for a 60-kilogram Vietnamese divided into three groups based on the rapidity with which 2,4-D and 2,4,5-T, might be translocated into portions consumed for food.*[1]

A. Foods into which very rapid movement is possible, not necessarily probable, and maximum concentration is attained immediately

	Dietary portions consumed g/person/day
Leafy green vegetable	52
Other vegetables	196
Condiment vegetable	40
Bananas	107
Other fruits	75
Total	470

B. Foods into which moderately rapid movement is possible, though not necessarily probable, and maximum concentration is attained within 1 week

Cereals	500
Fish and meat	311
Fish sauce	1
Spices	1
Coconut flesh	25
Coconut milk	12
Total	850

C. Foods into which movement is relatively slow and maximum concentration is attained within 2 weeks

Root vegetables	80
Beverage	5
Sugar and vegetable oils	95
Total	180

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[1] Components of diet and amounts consumed adapted from "Federation of Malaya Nutrition Survey", Report Interdepartmental Committee for Nutrition for National Defense, 1964, 365 pp. (Modified in consultation with Vietnamese students at Louisiana State University.)

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TABLE 6.—CALCULATION OF UPPER LIMITS FOR DAILY DOSE OF 2,4-D AND 2,4,5-T COMBINED WHEN ALL FOOD IS FULLY EXPOSED TO ONE AERIAL APPLICATION AT 26 LBS/A.[1]

[Maximum possible contamination, mg/kg/day]

Food Group	gm/person/day	Immediate	After 1 week	After 2 weeks
Group A	470	30	12	7
Group B	850	----------	22	13
Group C	180	----------	----------	3
Total		30	34	23E

[1] See Table 5.

deposited on foliage. The amount of residues of these chemicals that would penetrate into kernals of mature rice through palea and lemma is probably a very small percentage, if any, of the dose applied. There does not appear to be information on these points, however.

Probably the greatest potential hazard from contaminated food would be from ingesting leafy green vegetables, other vegetables, and fruits.

Much of the drinking water in the villages of Vietnam is from shallow, open wells and from rainwater collected from the roofs of thatched houses. Direct application of heavy rates of herbicide to these sources could result in the ingestion of substantial amounts of the chemicals in rainwater collected from roofs of houses. Assuming that about 270 mg of herbicide is applied per sq. ft. of surface, that water supplies are collected from rain falling on a roof having a total area of 200 sq. ft., and that all of the herbicide is washed off immediately after application and collected in containers holding 200 liters, a 60 kg person drinking 3 l. of water could get about 10 mg/kg/day. No information is available on the amounts of these chemicals that can be washed off a thatched roof by rainfall. However, data on rates of dissipation of 2,4-D and 2,4,5-T from dead litter material in pastures show rates of disappearance slower than for green tissues *(12)*. Thus, it appears reasonable to expect considerably less than 100 percent of the amount applied to be washed off a thatch roof treated with 2,4-D and 2,4,5-T. Even if it were all washed off, it appears to be unreasonable to expect it all to be captured in vessels having a combined capacity of only 200 liters. Therefore, any reasonable assumption would be that a person getting drinking water from such a source contaminated at the maximum rate possible would get much less than 10 mg/kg/day. [p. 63]

Drinking water from a shallow well contaminated at the maximum rate expected from a 26 lb/acre application, assuming a depth of 4 feet for water in the well, would amount to less than 0.5 mg/kg/day, and thus would pose no hazard.

Other possible routes of entry into humans from accidental direct application to non-target areas would be by inhalation and penetration through the skin. There is inadequate information available on these points to form any concept of the potential hazard of residues from these sources. Way *(17)* has suggested that there is little hazard of transport across the skin barrier. However, these materials are fat soluble which might encourage their percutaneous absorption. At least one study of the acute toxicity of the defoliant, Purple (esters of 2,4-D and 2,4,5-T), suggested that skin absorption of the animals tested occurred but was perhaps 10–20 times slower than absorption from the GI tract *(10)*. In the extreme situation of a nude, pregnant female, prone beneath an area of spraying of the defoliant, Orange, the maximum impingement of 20.2 mg/kg of 2,4,5-T on her skin might be expected. This should probably be viewed as equivalent to 2.0 mg/kg of an oral dose.

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SOME ECOLOGICAL EFFECTS

SUMMARY

Elimination of types of vegetation on which mammals, birds, fish, and insects and other species depend, can severely reduce or eliminate them from the treated habitat. However, altering the vegetation makeup may also benefit certain types of wildlife. The elimination of water hyacinth from some water bodies, for example, has proved a necessity for the survival of sport fishery programs.

2,4,5-T has been found to affect non-target organisms in a number of ways:

1. Although chickens, quail and maliard ducks appear to be relatively resistant to 2,4,5-T, the herbicide has been reported to reduce egg production in domestic chickens.

2. Some formulations of 2,4,5-T, such as certain esters, have been found to be quite toxic to fish and oysters.

3. The hydrocyanic acid content of sudan grass was found to increase 70 percent following treatment with 2,4,5-T. Nitrate levels in certain plants may increase up to 36 percent following treatment with 2,4,5-T, making them more toxic to mammals Increasing the toxicity of plants to wildlife might have important effects in nature.

5. 2,4,5-T may cause some species of microorganisms to decrease in number while having no effect upon other species. In soil, 2,4,5-T has been found to largely disappear in about three months.

2,4,5-T has been found to influence non-target organisms both directly and indirectly through habitat changes. The impact of 2,4,5-T on the principal classes of non-target organisms is presented in the following sections.

MAMMALS

Roe and Hymas *(12)* presented data to indicate that the acute oral toxicity LD_{50} of 2,4,5-T to various species of mammals was about 500 mg/kg.

2,4,5-T has some repellent action. When cottontail rabbits *(Sylvilagus floridanus)* were given a choice of either 2,4,5-T treated vegetation or untreated, the rabbits consumed almost none of the treated vegetation. *(14)*

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Applying 2,4,5-T or 2,4,5-T in combination with 2,4-D at recommended dosages for brush control in Michigan, resulted in killing the oak type vegetation and released the pine and encouraged a dense ground cover of grasses and other herbs, taller berry producing shrubs, and tree sprouts. *(7)* The low growing food and cover were ideal for deer, rabbits, grouse, and other forest animals.

Chemical brush control was carried out in power-line right-of-way with 2,4-D and 2,4,5-T applications. Woody brush was practically eliminated. White-tail deer *(Odocoileus virginianus)* have used both the treated and untreated areas and their use of both areas increased during the four years of investigation. *(2)* The deer made less use of the treated areas during the winter months because there was less food available. The deer fed most heavily in the treated areas in the spring and early summer on various grasses and herbs. Deer also bedded down in the treated areas in patches of sedge and grass. Numbers of cottontail rabbits were found to increase in the treated areas because of improved food and cover.

BIRDS

Fifty percent mortality in birds occurred for the following doses (2,4,5-T fed in the daily diet for less than 10 days): 5,000 ppm for young bobwhite quail *(Colinus virginianus)*; 5,000 ppm for young mallard ducks *(Anas platyrhynchos)*. *(4)* Approximate LD_{50}'s based on estimated food consumption, were: 9,000 mg/kg for the bobwhite; 21,000 mg/kg for the mallard.

The use of 2,4,5-T and 2,4-D for brush control under power lines improved the environment for ruffed grouse *(Bonasa umbellus) (2)*. The grouse were found on the edges within 150–200 feet of the right-of-way rather than on the right-of-way itself. This emphasized the importance of the right-of-way as a creator of edge effects. Wild turkeys *(Meleagris gallopavo)* were also observed to make effective use of the rights-of-way treated areas. The young turkeys were attracted to the openings for feeding on various insects which were more abundant on the grassy right-of-way than within the wooded areas.

Chickens were exposed daily for 14 days to grass treated with 2,4,5-T (15 percent active agent) at ¼ oz/gal of water and 2½ oz/gal. *(5)* The low 2,4,5-T treatment led to a 9 percent reduction in egg yield and the higher dosage to an 18 percent reduction but there was no change in the fertility or hatchability of the eggs. The exposed chickens also lost some weight.

FISH

The 24-hour LC_{50}* for rainbow trout *(Salmo gairdnerii)* exposed to 2,4,5-T was 12 ppm; however, Bohmont *(1)* reported a 48-hour LC_{50}

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for rainbow trout at 1.3 ppm. Bohmont also calculated the 48-hour LC_{50} for bluegills *(Lepomis macrochirus)* to be 0.50 ppm.

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* LC_{50}, median lethal concentration of a toxicant which kills 50 percent of the test organisms.

Young silver salmon *(Oncorhynchus kisutch)* exposed to a combination of 2,4,5-T and 2,4-D (about 10 percent of each chemical in the formulation) at concentrations of 50 ppm or more were observed to be "immediately distressed and would snap their jaws, dart about the aquarium, and leap out of the water before loss of equilibrium and death." *(8)*

Mullet *(Mugil cephalus)* exposed to 50 ppm of 2,4,5-T for 48 hours exhibited no noticeable effects. *(3)*

Table 1 gives 24- and 48-hour LC_{50}'s of bluegill sunfish to various 2,4,5-T formulation. *(9)* The esters appeared to be most toxic, probably due to better solubility. No attempt was made by Hughes and Davis to explain the wide variation in results obtained from different batches of the same formulation.

TABLE 1.—THE LC_{50} OF BLUEGILL SUNFISH TO 2,4,5-T FORMULATIONS. (9)

	24-hour	48-hour
Dimethylamine	144	144
Isooctyl ester*	31	31
Isooctyl ester*	28	26
Isooctyl ester*	10.4	10.4
Propylene glycol butyl ethyl ester	17	17
Butoxyethanol ester	1.4	1.4

*Different batches of the same formulation.

MOLLUSCS

The exposure of oysters *(Crassostrea virginica)* to 2.0 ppm of 2,4,5-T acid for 96 hours had no effect on shell growth. *(3)*

INVERTEBRATES

The minimum lethal dosages (ppm) which produced a kill exceeding 25 percent with 2,4,5-T are listed for the following fish food organisms: *Daphnia* 1.5; *Eucypris* 0.5; *Hyallella* 0.7; *Palaemonetes* 1.2; *Amphiagrion* 7.5; *Pachydiplax* and *Tramea* 8.0; and *Chironomus* 6.0. *(16)*

The exposure of brown shrimp *(Penaeus aztecus)* to 1.0 ppm of 2,4,5-T for 48 hours had no noticeable effects. *(3)*

PLANTS

Swanson and Shaw *(15)* demonstrated that the hydrocyanic acid content of sudan grass was increased by 70 percent in plots treated with 1 lb/acre of 2,4,5-T.

When 9 species of weeds were treated with sublethal dosages (0.25 lb/acre of 2,4,5-T, the nitrate content of the plants decreased from 5 to 32 percent in 4 species but increased from 3 to 36 percent [p. 67] in the other species. *(6)* The 36 percent increase occurred in *Impatiens biflora.*

The exposure of phytoplankton to 1.0 ppm of 2,4,5-T for 4 hours caused no decrease in growth. *(3)*

MICROORGANISMS

Magee and Colmer *(11)* reported that 2,4,5-T at 1,500 to 2,000 ppm produced inhibition of respiration to *Azotobacter,* however, 2,4,5-T was found not to affect *Streptomyces* at 2 and 50 lb/acre.

PERSISTENCE

2,4,5-T applied at a rate of ½ to 3 lb/acre was found to persist for 2 to 5 weeks with little or no leaching, under summertime conditions in a temperate climate and moist loam soil. *(10)* Sheets and Harris *(13)*, however, reported that 2,4,5-T generally persisted for about 3 months under moist soil conditions.

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